



**ready for take off**  
OTC opportunities



## Diapharm supports clients in all areas of product and dossier development



We develop innovative medicinal products, medical devices, cosmetics and biocides with added value and marketable regulatory strategies.

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## Medicinal products (by indication)

### Aches & Migraine

<b>Harpagophytum</b> (Devil's claw root)	600 mg	Film-coated tablet	Traditional HMP for relief of minor articular pain
<b>Tanacetum parthenium</b> (Feverfew herb)	100 mg	Capsule	For the prophylaxis of migraine headaches after serious conditions have been excluded by a medical doctor
<b>Tanacetum parthenium</b> (Feverfew herb)	200 mg	Film-coated tablet	For the prophylaxis of migraine headaches after serious conditions have been excluded by a medical doctor

### Cardiac Insufficiency

<b>Crataegus</b> (Hawthorn leaves with flowers)	450 mg	Film-coated tablet	Used to relieve symptoms of nervous cardiac complaints such as palpitations, after serious conditions have been excluded by a medical doctor
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### Climacteric Symptoms & Menstrual Disturbances

<b>Achillea millefolium</b> (Yarrow)	250 mg	Film-coated tablet	For symptomatic treatment of minor spasm associated with menstrual periods
<b>Agnus castus</b> (Chaste tree fruit)	4 mg	Film-coated tablet	For the relief of minor symptoms in the days before menstruation (premenstrual syndrome)
<b>Capsella bursa-pastoris</b> (Shepherd's purse)	400 mg	Coated tablet	For the reduction of heavy menstrual bleeding in women with regular menstrual cycles, after serious conditions have been excluded by a medical doctor
<b>Cimicifuga</b> (Black cohosh rhizome)	6.5 mg	Film-coated tablet	Used to relieve the symptoms of the menopause, such as hot flashes, night sweats and temporary changes in mood
<b>Hypericum, Cimicifuga</b> (St. John's Wort herb, Black cohosh rhizome)	300 mg, 6.4 mg	Coated tablet	Used for the relief of symptoms of the menopause, including hot flashes, night sweat, slightly low mood and mild anxiety

## Medicinal products (by indication)

### Convalescence

<b>Eleutherococcus</b> (Siberian ginseng)	120 mg	Capsule	For symptoms of asthenia such as fatigue and weakness
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### Cough & Cold

<b>Pelargonium</b> (Pelargonium root)	20 mg	Film-coated tablet	For the symptomatic treatment of common cold
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### Gastro-intestinal disorders / Digestion

<b>Achillea millefolium</b> (Yarrow)	250 mg	Film-coated tablet	For symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence
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### Low Mood

<b>Hypericum</b> (St. John's Wort herb)	425 mg	Coated tablet	For the short term treatment of symptoms in mild depressive disorders
<b>Hypericum, Valeriana</b> (St. John's Wort herb, Valerian root)	120 mg, 56 mg	Coated tablet	For the treatment of mental exhaustion (fatigue) and related sleep disturbance.

## Medicinal products (by indication)

### Nervous Tension, Sleep Disorder & Symptoms of Stress

<b>Passiflora</b> (Passionflower herb)	425 mg	Coated tablet	For relief of mild symptoms of mental stress and to aid sleep
<b>Passiflora, Valeriana</b> (Passionflower herb, Valerian root)	250 mg, 125 mg	Coated tablet	Used for the temporary relief of sleep disturbances due to symptoms of mild anxiety
<b>Valeriana</b> (Valerian root)	450 mg	Coated tablet	For the relief of mild nervous tension and sleep disorders
<b>Valeriana, Melissa, Passiflora</b> (Valerian root, Melissa leaf, Passionflower herb)	125 mg, 112.5 mg, 80 mg	Coated tablet	Used for the temporary relief of symptoms of mild anxiety, to aid sleep and for mild digestive complaints, such as bloating and flatulence

### Prostate & Urinary Tract

<b>Betula</b> (Birch leaves) powder + extract	107 mg + 42.4 mg	Coated tablet	To increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints, exclusively based upon long-standing use
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### Venous Diseases

<b>Vitis vinifera</b> (Red vine leaf)	360 mg	Film-coated tablet	For treatment of chronic venous insufficiency, which is characterised by swollen legs, varicose veins, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calves
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### Weight Loss

<b>Fucus</b> (Bladderwrack)	130 mg	Film-coated tablet	Adjuvant to reduced calorie diet to help weight loss in overweight adults, after serious conditions have been excluded by a doctor
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## Medicinal products (by indication)

Skin		
<b>Callus Remover Instant</b>	Solution	Intensive callus remover for the relief of pain caused by calluses
<b>Corn Remover</b>	Pen	Effective express corn reduction and fast pain relief
<b>NoLice</b>	Mousse	Treatment and prevention of head lice
<b>NoLice After Treatment</b>	Shampoo	Complementary use during and after the treatment of head lice
<b>NoLice Defence</b>	Spray	Protection against head lice
<b>NoSkito (Natural PMD+)</b>	Repellent	Repellent against mosquitos and ticks



## ■ Harpagophytum 600 mg film-coated tablet



High dosage of a traditionally used herbal medicine to relieve rheumatic or articular pain.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication</b>	<p>UK: Traditional herbal medicinal product used for the relief of backache, rheumatic or muscular pain, general aches and pain in the muscles and joints.</p> <p>HMPC monograph: Traditional HMP for relief of minor articular pain.</p>
<b>Active substance:</b>	600 mg dry extract of <b>Harpagophytum (Devil's claw root)</b> (DER 1.5 - 2.5 : 1), extraction solvent: water
<b>Dosage form:</b>	Film-coated, oblong, white tablet ca. 950 mg
<b>Dosage:</b>	1 - 2 x 2 film-coated tablets / day = 1200-2400 mg dry extract
	HMPC monograph requirements: Dry extract (1.5-2.5 : 1; water): 300 mg to 2.4 g divided in 2 to 3 doses
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	In PVC/PVDC/Alu: 36 months    25° C / 60 % RH 12 months    30° C / 60 % RH 6 months      40° C / 75 % RH
<b>Dossier:</b>	CTD marketing authorisation documentation incl. stability testing for 36 months is available
<b>Product USPs:</b>	High dosage

## Tanacetum 100 mg capsule



Attractive indication for the prophylaxis of migraine headaches.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication</b>	HMPC monograph: Traditional herbal medicinal product for the prophylaxis of migraine headaches after serious conditions have been excluded by a medical doctor. Exclusively based upon long-standing use.
<b>Active substance:</b>	100 mg powdered <b>Tanacetum parthenium (Feverfew herb)</b>
<b>Dosage form:</b>	gelatine-free hard capsule size 1
<b>Dosage:</b>	1 - 6 capsules / day HMPC monograph requirements: 100 - 600 mg daily
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	Storage conditions acc. to ICH: 36 months 25° C / 60 % RH 12 months 30° C / 60 % RH 6 months 40° C / 75 % RH
<b>Dossier:</b>	CTD marketing authorisation documentation incl. stability testing for 36 months is available
<b>Product USPs:</b>	Attractive indication – migraine prevention Prophylaxis and adjunctive therapy



## Tanacetum 200 mg forte film-coated tablet



Attractive indication for the prophylaxis of migraine headaches.

High dosage!

<b>Regulatory classification:</b>	Medicinal product
<b>Indication</b>	HMPC monograph: Traditional herbal medicinal product for the prophylaxis of migraine headaches after serious conditions have been excluded by a medical doctor. Exclusively based upon long-standing use.
<b>Active substance:</b>	200 mg powdered <b>Tanacetum parthenium (Feverfew herb)</b>
<b>Dosage form:</b>	Film-coated tablet
<b>Dosage:</b>	1 - 3 tablets / day HMPC monograph requirements: 100 - 600 mg daily
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	Storage conditions acc. to ICH: 36 months 25° C / 60 % RH 12 months 30° C / 60 % RH 6 months 40° C / 75 % RH
<b>Dossier:</b>	CTD marketing authorisation documentation is available
<b>Product USPs:</b>	High dosage – forte! Attractive indication – migraine prevention Prophylaxis and adjunctive therapy Easy to handle – 1-3 tablets / day

## ■ Crataegus 450 mg film-coated tablet



Traditional herbal medicine with an attractive OTC indication for the relief of nervous cardiac complaints.

<b>Regulatory classification:</b>	Medicinal product
<b>Targeted indication</b>	Traditional herbal medicinal product used to relieve symptoms of temporary nervous cardiac complaints (e.g. palpitations, perceived extra heart beat due to mild anxiety) after serious conditions have been excluded by a medical doctor. The product is exclusively based upon long-standing use.
<b>Active substance:</b>	450 mg dry extract of <b>Crataegus (Hawthorn leaves with flowers)</b> (4 - 7 : 1), extraction solvent: ethanol 45 % (V/V)
<b>Dosage form:</b>	coated tablet Diameter: ca. 13 mm Height: ca. 7 mm Weight: ca. 1 g
<b>Dosage:</b>	2 coated tablets / day
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	3 production scale batches: 36 months 25° C / 60 % RH 12 months 30° C / 65 % RH 6 months 40° C / 75 % RH
<b>Dossier:</b>	CTD marketing authorisation documentation with 36 months stability is available
<b>Product USPs:</b>	Attractive cardiac indication - OTC

## ■ **Achillea millefolium 250 mg (Gyn) film-coated tablet**



OTC-innovation with a rediscovered indication for menstrual discomfort. Traditional herbal medicine with natural efficacy for the relief of menstrual spasms.

<b>Regulatory classification:</b>	Medicinal product
<b>Targeted indication (HMPC):</b>	Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods. For use in the specified indication exclusively based upon longstanding use. From 12 years up.
<b>Indication granted by BfArM (Germany):</b>	Traditionelles pflanzliches Arzneimittel zur symptomatischen Behandlung leichter Krämpfe während der Menstruation. Ab 12 Jahre.
<b>Active substance:</b>	250 mg dry extract <b>Achillea millefolium (Yarrow)</b> (DER 5 - 10 : 1), extraction solvent: water
<b>Dosage form:</b>	Film-coated tablet
<b>Dosage:</b>	1 tablet 2 - 3 times daily
<b>Primary Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Marketing authorisation:</b>	THMP registration in accordance with Directive 2004/24 EC
<b>Intended shelf-life:</b>	3 years
<b>Stability testing:</b>	25° C / 60 % RH (36 months) 30° C / 65 % RH (12 months) 40° C / 75 % RH (6 months)
<b>Dossier:</b>	Germany: Marketing authorisation available. Other countries: CTD marketing authorisation dossier, ready for application
<b>Product USPs:</b>	OTC-innovation with indication menstrual discomfort Natural efficacy

## ■ Agnus castus 4 mg film-coated tablet



A herbal medicine for the relief of PMS symptoms. Small, easy-to-swallow tablet with a long-standing tradition for a very attractive indication.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication</b>	Traditional herbal medicinal product for the relief of minor symptoms in the days before menstruation (premenstrual syndrome), exclusively based upon long-standing use.
<b>Target population:</b>	Adults
<b>Active substance:</b>	4 mg dry extract of fruits of <b>Vitex agnus castus (Chaste tree fruit)</b> (7 - 13 : 1), extraction solvent: ethanol 60 % (m/m)
<b>Dosage:</b>	1 film-coated tablet / day: round, red tablet (Ø 9 mm)
<b>Packaging:</b>	Blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	Stability data acc. to ICH conditions (3 production scale batches): 48 months    25° C / 60 % RH 6 months    40° C / 75 % RH
<b>Dossier:</b>	Marketing authorisation documentation (CTD-dossier) available
<b>Product USPs:</b>	Natural PMS product Attractive women's health indication Small tablets Only one a day

## ■ Capsella 400 mg film-coated tablet



A unique herbal OTC-product based on a rediscovered medicinal plant. Relieves menstrual discomfort by reducing heavy menstrual bleeding.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication (HMPC):</b>	Traditional herbal medicinal product for the reduction of heavy menstrual bleeding in women with regular menstrual cycles.
<b>Indication granted by BfArM (Germany):</b>	Traditionelles pflanzliches Arzneimittel zur Verminderung starker Menstruationsblutungen bei Frauen mit regelmäßigen Menstruationszyklen.
<b>Active substance:</b>	400 mg dry extract <b>Capsella bursa-pastoris (Shepherd's purse)</b> (DER 5 - 9 : 1, extraction solvent ethanol 25 % V/V)
<b>Dosage form:</b>	Coated tablet
<b>Dosage:</b>	1 tablet 3 times daily
<b>Primary Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Marketing authorisation:</b>	THMP registration in accordance with Directive 2004/24 EC
<b>Intended shelf-life:</b>	3 years
<b>Stability testing:</b>	25° C / 60 % RH (36 months) 30° C / 65 % RH (12 months) 40° C / 75 % RH (6 months)
<b>Dossier:</b>	Germany: Marketing authorisation available. Other countries: CTD marketing authorisation dossier, ready for application
<b>Product USPs:</b>	Natural PMS product Attractive women's health indication Small tablets Only one a day

## ■ Cimicifuga 6.5 mg film-coated tablet



Natural OTC-Product with an attractive women's health indication for menopausal discomfort. Traditionally used to relieve menopausal symptoms such as hot flushes and profuse sweating.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication:</b>	Well-established Use: For the relief of menopausal complaints such as hot flushes and profuse sweating.  Traditional Use (only in some countries, e.g. UK): Traditional herbal medicinal product used to relieve the symptoms of the menopause, such as hot flushes, night sweats and temporary changes in mood.
<b>Active substance:</b>	6.5 mg dry extract of Cimicifuga (Black cohosh rhizome) (4.5 - 8.5 : 1), extraction solvent: ethanol 60 % (V/V)
<b>Dosage form:</b>	Film-coated, round, white tablet Diameter: 9 mm Height: 4 mm Weight: ca. 260 mg
<b>Dosage:</b>	1 film-coated tablet / day
<b>Packaging:</b>	Blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	Stability data package for production scale batches available according to ICH: 25 °C / 60 % RH 30 °C / 60 % RH 40 °C / 75 % RH
<b>Dossier:</b>	Marketing authorisation documentation (CTD-dossier) incl. stability for 48 months is available
<b>Product USPs:</b>	Attractive women's health indication Natural OTC product Only once a day



## ■ Hypericum 300 mg + Cimicifuga 6.4 mg coated tablet



Unique combination product to ease menopausal symptoms such as hot flushes and low mood. Comfortable once-a-day dosage.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication:</b>	Traditional herbal medicinal product used for the relief of symptoms of the menopause, including hot flushes, night sweats, also profuse sweats, slightly low mood and mild anxiety mild anxiety based on traditional use only
<b>Active substance:</b>	300 mg dry extract of <b>Hypericum (St. John´s Wort)</b> (3.5 - 6.0 : 1), extraction solvent: ethanol 60 % (m/m)  6.4 mg dry extract of <b>Cimicifuga (Black cohosh rhizome)</b> (4.5 - 8.5 : 1), extraction solvent: ethanol 60 % (V/V)
<b>Dosage form:</b>	Coated tablet Diameter: ca. 13 mm (tablet core: 12 mm) Height: ca. 7.7 mm Weight: ca. 1 g
<b>Dosage:</b>	1 coated tablet / day
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	ICH storage conditions (production scale batches): 36 months 25° C / 60 % RH 12 months 30° C / 65 % RH 6 months 40° C / 75 % RH
<b>Dossier:</b>	CTD registration documentation incl. stability testing for 36 months is available
<b>Product USPs:</b>	Unique combination product Only one a day DCP registration in 7 countries

## ■ Eleutherococcus 120 mg capsule



Once-a-day dosage with easy to swallow capsules. Traditionally indicated to help with asthenia and convalescence.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication:</b>	HMPC monograph and list entry: Traditional herbal medicinal product for symptoms of asthenia such as fatigue and weakness, exclusively based upon long-standing use.
<b>Active substance:</b>	120 mg dry extract of <b>Eleutherococcus (Siberian ginseng root)</b> (16 - 25 : 1), extraction solvent: ethanol 30 % (V/V)
<b>Dosage form:</b>	Hard capsule size 4 advantage: very small Capsule filling mass only ca. 160 mg
<b>Dosage:</b>	1 capsule / day
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	Storage conditions acc. to ICH: 36 months 25° C / 60 % RH 12 months 30° C / 60 % RH 6 months 40° C / 75 % RH
<b>Dossier:</b>	CTD marketing authorisation documentation incl. stability testing for 36 months is available
<b>Product USPs:</b>	Small capsule – easy to swallow Easy to handle dosage – 1 capsule per day

## ■ Pelargonium 20 mg film-coated tablet



Herbal cough and cold medicine for adults and children, free from alcohol and preservatives.  
Attractive CoG combined with a premium appearance.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication:</b>	<p>HMPC monograph: Traditional herbal medicinal product for the symptomatic treatment of common cold, exclusively based upon long-standing use.</p> <p>Granted in UK: Traditional herbal medicinal product used to relieve the symptoms of upper respiratory tract infections including the common cold, such as sore throat, cough and blocked or runny nose, based on traditional use only.</p>
<b>Active substance:</b>	20 mg dry extract of <b>Pelargonium sidoides / reniforme radix</b> (4 - 7 : 1), extraction solvent: ethanol 14 % (V/V)
<b>Dosage form:</b>	film-coated, round, red tablet · 400 mg, ø: 10 mm; height: 5 mm
<b>Dosage:</b>	<p>Adults and adolescents: 3 tablets / day</p> <p>Children 6 - 12 years of age: 2 tablets / day, according to HMPC monograph requirements</p>
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability Testing:</b>	<p>Storage conditions acc. to ICH:</p> <p>60 months    25° C / 60 % RH</p> <p>9 months     30° C / 65 % RH</p> <p>6 months     40° C / 75 % RH</p>
<b>Dossier:</b>	CTD marketing authorisation documentation is available with 60 months stability testing
<b>Product USPs:</b>	<p>Suitable for adults and children</p> <p>Attractive CoGs</p>

## ■ **Achillea millefolium 250 mg (Gastro)** film-coated tablet



OTC-innovation with a rediscovered indication for the relief of gastro-intestinal complaints including bloating and flatulence. Traditional herbal medicine with natural efficacy.

<b>Regulatory classification:</b>	Medicinal product
<b>Targeted indication:</b>	Traditional herbal medicinal product for the symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.
<b>Active substance:</b>	250 mg dry extract <b>Achillea millefolium (Yarrow)</b> (DER 5 - 10 : 1), extraction solvent: water
<b>Dosage form:</b>	Film-coated tablet
<b>Dosage:</b>	1 - 2 tablets 3 or 4 times daily
<b>Packaging:</b>	Blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Intended shelf-life:</b>	3 years
<b>Marketing authorisation:</b>	THMP registration in accordance with Directive 2004/24 EC
<b>Timelines:</b>	Dossier ready for application
<b>Opportunities:</b>	Exclusive licenses in many EU-countries
<b>Product USPs:</b>	OTC-innovation for treatment of spasm, bloating and flatulence Natural efficacy

## ■ Hypericum 425 mg coated tablet



Natural OTC product indicated to relieve symptoms of mild depressive disorders.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication:</b>	<p>HMPC monograph (Well-established Use): Herbal medicinal product for the short term treatment of symptoms in mild depressive disorders.</p> <p>Traditional Use (only UK): Traditional herbal medicinal product used to relieve the symptoms of slightly low mood and mild anxiety.</p>
<b>Active substance:</b>	425 mg dry extract of <b>Hypericum (St. John´s Wort herb)</b> (3.5 - 6.0 : 1), extraction solvent: ethanol 60 % (m/m), corresp. to 750 - 1300 µg total hypericins, calc. as hypericin (HPLC)
<b>Dosage form:</b>	Coated tablet, yellow Diameter: 13.4 mm · Height: 7.7 mm · Weight: 1.1 g
<b>Dosage:</b>	1 - 2 coated tablets / day
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	<p>(3 pilot scale batches): 36 months 25° C / 60 % RH 12 months 30° C / 60 % RH 6 months 40° C / 75 % RH</p> <p>(2 production scale batches): 48 months 25° C / 60 % RH</p> <p>Quantified markers: rutin, hypericines, hyperforin</p>
<b>Dossier:</b>	CTD marketing authorisation documentation incl. stability testing for 48 months is available
<b>Product USPs:</b>	Natural OTC product

## ■ Hypericum 120 mg + Valeriana 56 mg coated tablet



Unique combination product indicated for mental exhaustion and related sleep disturbance.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication:</b>	Traditional medicinal product used for the treatment of mental exhaustion (fatigue) and related sleep disturbance.
<b>Indication granted by BfArM (Germany):</b>	Traditionelles pflanzliches Arzneimittel zur Behandlung von seelischen Erschöpfungszuständen und damit verbundenen Schlafstörungen.
<b>Active substance:</b>	120 mg dry extract of Hypericum (St. John´s Wort herb) (3.5 - 6 : 1), extraction solvent: ethanol 60 % (m/m) 56 mg dry extract of Valeriana (Valerian root) (3 - 6 : 1), extraction solvent: ethanol 70 % (V/V)
<b>Dosage form:</b>	Coated tablet Diameter: ca. 11.3 mm (tablet core: 10 mm) Height: ca. 6 mm Weight: ca. 590 mg
<b>Dosage:</b>	1 - 3 coated tablets / day
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	ICH storage conditions (pilot scale batches): 36 months 25° C / 60 % RH 12 months 30° C / 65 % RH 6 months 40° C / 75 % RH
<b>Dossier:</b>	CTD registration documentation incl. stability testing for 36 months is available
<b>Product USPs:</b>	Unique combination product License rights for granted German and Austrian registrations available



## ■ Passiflora 425 mg coated tablet



Traditional herbal remedy to relieve mental stress.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication:</b>	HMPC monograph: Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep, exclusively based upon long-standing use.
<b>Active substance:</b>	425 mg dry extract of <b>Passiflora (Passionflower herb)</b> (5 - 7 : 1), extraction solvent: ethanol 50 % (V/V)
<b>Dosage form:</b>	Coated tablet Diameter: 13.3 mm (tablet core: 12 mm) Height: 7.7 mm Weight: 1 g
<b>Dosage:</b>	1 - 3 x daily 1 coated tablet Dosage conforms to requirements of the HMPC monograph
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	ICH storage conditions (3 production scale batches): 48 months 25° C / 60 % RH 12 months 30° C / 65 % RH 6 months 40° C / 75 % RH
<b>Dossier:</b>	CTD marketing authorisation documentation incl. stability testing for 48 months is available
<b>Product USPs:</b>	Natural product against mental stress

## ■ Passiflora 250 mg + Valeriana 125 mg coated tablet



Attractive combination of sedative plants to relieve anxiety and sleep disturbances.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication:</b>	HMPC monograph: Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep, exclusively based upon long-standing use.
<b>Active substance:</b>	250 mg dry extract of <b>Passiflora (Passionflower herb)</b> (5 - 7 : 1), extraction solvent: ethanol 50 % (V/V)  125 mg dry extract of <b>Valeriana (Valerian root)</b> (3 - 6 : 1), extraction solvent: ethanol 70 % (V/V)
<b>Dosage form:</b>	Coated tablet Diameter: 13.2 mm (tablet core: 12 mm) Height: 6.8 mm Weight: 935 mg
<b>Dosage:</b>	1 - 2 x daily 2 coated tablets Dosage conform with the requirements of the Commission E monographs
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	ICH storage conditions: 48 months 25° C / 60 % RH 12 months 30° C / 65 % RH 6 months 40° C / 75 % RH
<b>Dossier:</b>	CTD marketing authorisation documentation incl. stability testing for 48 months is available
<b>Product USPs:</b>	Attractive combination of sedative plants

## ■ Valeriana 450 mg coated tablet



High dosage of a popular herbal product to relieve mild nervous tension and sleep disorders.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication:</b>	HMPC monograph (Well-established Use): Herbal medicinal product for the relief of mild nervous tension and sleep disorders
<b>Active substance:</b>	450 mg dry extract of <b>Valeriana (Valerian root)</b> (3 - 6 : 1), extraction solvent: ethanol 70 % (V/V)
<b>Dosage form:</b>	Coated tablet Diameter: 13.4 mm (tablet core: 12 mm) Height: 7.7 mm Weight: 1.1 g
<b>Dosage:</b>	1 - 3 coated tablets / day 1 coated tablet: 450 mg native extract (drug / extract ratio (DER) = 3 - 6 : 1) Corresponding to the average DER (4.5 : 1) = ca. 2 g drug HMPC monograph requirements: 2 - 3 g drug once to several times a day
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	Storage conditions (3 production scale batches): 48 months 25° C / 60 % RH 12 months 30° C / 65 % RH 6 months 40° C / 75 % RH
<b>Dossier:</b>	CTD marketing authorisation documentation incl. stability testing for 48 months is available

## ■ Valeriana 125 mg + Passiflora 80 mg + Melissa 112.5 mg coated tablet



Attractive combination of sedative plants to relieve mild nervous tension and sleep disorders.

<b>Regulatory classification:</b>	Medicinal product						
<b>Indication:</b>	<p>Granted in UK: A traditional herbal medicinal product used for the temporary relief of symptoms of mild anxiety, to aid sleep and for mild digestive complaints, such as bloating and flatulence, based on traditional use only.</p> <p>Granted in Austria: Traditional herbal medicinal product used for for the relief of nervous tension and difficulties to fall asleep, exclusively based upon long-standing use.</p>						
<b>Active substance:</b>	<p>125 mg dry extract of <b>Valeriana (Varlerian root)</b> (3 - 6 : 1), extraction solvent: ethanol 70 % (V/V)</p> <p>112.5 mg dry extract of <b>Melissa leaf</b> (4 - 6 : 1), extraction solvent: methanol 30 % (V/V)</p> <p>80 mg dry extract of <b>Passiflora (Passionflower herb)</b>, (5 - 7 : 1), extraction solvent: ethanol 50 % (V/V)</p>						
<b>Dosage form:</b>	<p>Coated tablet Diameter: 12.2 mm · Height: 5.5 mm · Weight: 700 mg</p>						
<b>Dosage:</b>	Up to 3 x daily 1-2 coated tablets						
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)						
<b>Stability testing:</b>	<p>ICH storage conditions:</p> <table> <tr> <td>60 months</td> <td>25° C / 60 % RH</td> </tr> <tr> <td>6 months</td> <td>30° C / 60 % RH</td> </tr> <tr> <td>6 months</td> <td>40° C / 75 % RH</td> </tr> </table>	60 months	25° C / 60 % RH	6 months	30° C / 60 % RH	6 months	40° C / 75 % RH
60 months	25° C / 60 % RH						
6 months	30° C / 60 % RH						
6 months	40° C / 75 % RH						
<b>Dossier:</b>	CTD marketing authorisation documentation incl. stability testing for 60 months is available						
<b>Product USPs:</b>	Attractive combination of sedative plants						

## ■ Betula 107 mg coated tablet



A traditional herbal medicine to increase the amount of urine, thus helping to flush the urinary tract.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication:</b>	HMPC monograph: Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints, exclusively based upon long-standing use.
<b>Active substance:</b>	107 mg powdered <b>Betula (Birch leaves)</b> 42.4 mg dry extract of <b>Birch leaves</b> (DER = 4 - 8 : 1) extraction solvent: water
<b>Dosage form:</b>	Coated tablet, white
<b>Dosage:</b>	3 x 1 tablet / day
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	36 months    25° C / 60 % RH 12 months    30° C / 65 % RH
<b>Dossier:</b>	Marketing authorisation documentation (CTD) ready for filing

## ■ Vitis vinifera 360 mg film-coated tablet



OTC-Opportunity: Highly dosed herbal treatment for venous insufficiency. Very competitive CoGs.

<b>Regulatory classification:</b>	Medicinal product
<b>Indication:</b>	HMPC monograph (Well-established Use): Herbal medicinal product for treatment of chronic venous insufficiency, which is characterised by swollen legs, varicose veins, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calves.
<b>Indication granted by BfArM (Germany):</b>	Pflanzliches Arzneimittel zur Behandlung von Beschwerden bei Erkrankungen der Beinvenen (chronische Veneninsuffizienz) angewendet, zum Beispiel Beinschwellungen, Krampfadern, einem Gefühl von Schwere, Schmerzen, Müdigkeit, Juckreiz, Spannung und Krämpfen in den Waden.
<b>Active substance:</b>	360 mg dry extract of <b>Vitis vinifera (Red Vine Leaf)</b> (4 - 6 : 1), extraction solvent: water
<b>Dosage form:</b>	Film-coated, oblong tablet ca. 1 x 8 mm
<b>Dosage:</b>	1-2 x 1 tablet / day (conform with HMPC monograph)
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Stability testing:</b>	Storage conditions: 36 months 25° C / 60 % RH 12 months 30° C / 65 % RH 6 months 40° C / 75 % RH
<b>Dossier:</b>	CTD marketing authorisation documentation available, incl. stability data over 36 months
<b>Product USPs:</b>	High-dose Generic Red Vine Leaf as OTC-opportunity



## ■ Fucus 130 mg film-coated tablet



A rediscovered medicinal plant with the attractive indication of weight loss in overweight adults.

<b>Regulatory classification:</b>	Medicinal product
<b>Targeted indication:</b>	Traditional herbal medicinal product used as an adjuvant to reduced calorie diet to help weight loss in overweight adults, after serious conditions have been excluded by a medical doctor.
<b>Indication granted by BfArM (Germany):</b>	Traditionelles pflanzliches Arzneimittel zur Ergänzung einer kalorienreduzierten Gewichtsreduktionsdiät bei übergewichtigen Erwachsenen, nachdem durch einen Arzt schwerwiegende Grunderkrankungen ausgeschlossen wurden.
<b>Active substance:</b>	130 mg powdered herbal substance <b>Fucus vesiculosus (Bladderwrack)</b>
<b>Dosage form:</b>	Film-coated round tablet Diameter: 9 mm Height: 5 mm
<b>Dosage:</b>	Twice daily 1 tablet with a glass of water, 2 hours before meals
<b>Packaging:</b>	Binary blister of PVC/PVDC and aluminium (PVC/PVDC – alu)
<b>Marketing authorisation:</b>	THMP registration in accordance with Directive 2004/24 EC
<b>Intended shelf-life:</b>	2 years
<b>Stability testing:</b>	25° C / 60 % RH (36 months) 30° C / 65 % RH (12 months) 40° C / 75 % RH (6 months)
<b>Dossier:</b>	CTD marketing authorisation documentation ready for application
<b>Product USPs:</b>	Unique indication Fucus – rediscovered medicinal plant Conform to monograph Only one tablet twice a day

## Callus Remover Instant solution



Removes excessive hard skin and soothes pressure pain caused by calluses. Also prevents the development of cracks and calluses.



<b>Regulatory classification:</b>	Medical Device
<b>Intended Purpose (Indication):</b>	Intensive callus remover for the relief of pain caused by calluses.
<b>Ingredients:</b>	4,9% Potassium Hydroxide
<b>Dosage:</b>	Apply the solution generously to a cotton pad or absorbent gauze until it is completely soaked through and place it on the callus. Leave to take effect for up to a maximum of 10 minutes, depending on the thickness of the callus. Remove the callus using the special spatula provided.
<b>Packaging:</b>	50 ml PE-bottle with child-resistant cap, incl. special spatula
<b>Marketing authorisation:</b>	CE-label, Medical Device Class IIa ready to be marketed
<b>Stability testing:</b>	Available, the product has a shelf life of 24 months when stored between 10°C and 25°C
<b>Certification:</b>	In European Union countries, this product will be classified as a Class IIa Medical Device under the Council Directive 93/42/EEC. A full Technical File exists.
<b>Product USPs:</b>	Highly effective solution, works from the first application Fast acting Soothes pressure pain Prevents the development of cracks and calluses

## ■ Corn Remover Pen



Effective corn reduction and fast pain relief. Safe and easy to use.

<b>Regulatory classification:</b>	Medical Device
<b>Intended Purpose (Indication):</b>	Helps to remove and relieve painful corns.
<b>Ingredients:</b>	Formulation with 12% salicylic acid
<b>Dosage:</b>	Apply 2 to 4 times a day directly on the corn Application period: up to 30 days
<b>Packaging:</b>	2 ml twist pen for up to 40 applications
<b>Marketing authorisation:</b>	CE-label, Medical Device class IIa ready to be marketed
<b>Stability testing:</b>	Available, the product has a shelf life of 36 months when stored between 15°C and 25°C
<b>Certification:</b>	In European Union countries, this product is classified as a Class IIa Medical Device under the Council Directive 93/42/EEC. A full Technical File exists.
<b>Product USPs:</b>	Highly effective corn removal Relieves pressure pain from corns Noticeable results within 4 days Safe and easy to use – anytime, anywhere Works from the first application Medical Device Class IIa

## ■ NoLice mousse



Medical device to treat and prevent head lice: the dosage form as a mousse – like a styling mousse – is easy to use, quick and child-friendly. Highly effective – only one treatment necessary. Acts also prophylactically during leave on period.

<b>Regulatory classification:</b>	Medical Device
<b>Intended Purpose (Indication):</b>	Treatment and prevention of head lice
<b>Ingredients:</b>	Natural based concept
<b>Dosage Form:</b>	Mousse
<b>Dosage:</b>	Application like a styling mousse, can remain in the hair all day long Different types of application: <ul style="list-style-type: none"> <li>• Short application: Rinse out after 30 minutes (effective on lice)</li> <li>• Overnight / During-the-day usage: Leave on for 8 hours, rinse out (effective on lice and nits)</li> </ul>
<b>Packaging:</b>	150 ml / 250 ml alu can with foam applicator
<b>Stability testing:</b>	Available
<b>Status:</b>	CE-label, Medical Device Class IIa, Q4 2019, ready to be marketed (at the moment Medical Device Class I)
<b>Product USPs:</b>	Kills 100% of lice in only 30 minutes Effective against lice & nits For adults and children from the age of one year No resistances, no parabens, no silicones

## ■ NoLice After Treatment shampoo



For complementary use during and after the treatment against head lice:  
Soothes the scalp, reduces irritation and promotes skin regeneration.

<b>Regulatory classification:</b>	Cosmetic
<b>Intended Purpose (Indication):</b>	Reducing symptoms like itching and tingling
<b>Ingredients:</b>	Natural based concept
<b>Dosage Form:</b>	Shampoo
<b>Dosage:</b>	Suitable for daily application
<b>Packaging:</b>	Bottle with flip-top cap
<b>Stability testing:</b>	Available
<b>Product USPs:</b>	<ul style="list-style-type: none"> <li>Soothes the scalp</li> <li>Reduces irritation</li> <li>Eases lice combing</li> <li>Suitable for daily use</li> <li>Dermatologically tested</li> <li>Without allergens, silicones and solvents (alcohol free)</li> </ul>

## ■ NoLice Defence spray



Invisible protection against head lice, keeps lice away for up to 12 hours. Easy application as a spray, suitable for children from 1 year

<b>Regulatory classification:</b>	Biocide
<b>Intended Purpose (Indication):</b>	Prevents an infestation and re-transmission of head lice
<b>Ingredients:</b>	Natural based concept
<b>Dosage Form:</b>	Spray
<b>Dosage:</b>	Spray on the hair
<b>Packaging:</b>	Bottle with spray applicator
<b>Stability testing:</b>	Available
<b>Product USPs:</b>	<p>Up to 12 hours of reliable protection against lice</p> <p>Simple &amp; targeted application</p> <p>Gentle to scalp and hair</p> <p>Dermatologically tested</p>

## ■ NoSkito repellent range



Natural and very effective repellent line against mosquitos and ticks. Special, successful formulations for adults, children and babies.

<b>Regulatory classification:</b>	Biocide
<b>Target population:</b>	Adults and for children over the age of 12 months. For children over the age of 6 months (repellent lotion for babies).
<b>Active substance:</b>	Nature based, water soluble active formula
<b>Product range:</b>	Repellent spray Repellent tropical spray Repellent lotion Repellent sensitive lotion Repellent lotion with sun protection SPF 25 Repellent lotion with after sun effect Repellent lotion for babies Repellent gel Tick repellent spray ... and more
<b>Packaging:</b>	According to your needs
<b>Shelf life:</b>	Stability data available
<b>Availability:</b>	Licenses and products available; Sales and distribution ready to start with interested parties; adaption to formulations and packaging possible; contract manufacturing
<b>Product USPs:</b>	Intensive protection against ticks and mosquitos (up to 8 hours) Sweat solid and water resistant Skin friendly Efficacy successfully tested For adults, children and babies



