SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Myopridin 3 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 3.02 mg pridinol (as 4 mg pridinol mesilate).

Excipient(s) with known effect
One tablet contains 143.5 mg lactose (as monohydrate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

White, round tablet with a score line on one side
Diameter 9.0 - 9.2 mm
Height 2.5 - 2.7 mm
The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Central and peripheral muscle spasms: lumbar pain, torticollis, general muscle pain, in adults.

4.2 Posology and method of administration

Posology

The recommended dose is 1.5 – 3 mg pridinol 3 times daily

The duration of administration is decided by the treating doctor.

Administration is independent of meals, with the onset of the effect being faster when the medicinal product is taken before meals.

Patients who suffer from hypotension should take the tablets after meals to reduce the risk of fainting.

Children and adolescents
No data are available

Method of administration
For oral use.
The tablets should be taken with sufficient fluid (e.g. 1 glass of water) and not chewed.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Glaucoma
- Prostate hypertrophy
- Syndrome with urinary retention
- Gastrointestinal obstructions
- Arrhythmia
- First trimester of pregnancy

4.4 Special warnings and precautions for use

The medicinal product must be used with caution in the elderly, and in patients with severe renal and/or hepatic insufficiency, because higher and/or longer-lasting blood levels must be expected.

In patients who suffer from hypotension, the risk of circulatory problems (fainting) may be increased.

Myopridin contains lactose. Patients with the rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

4.5 Interaction with other medicinal products and other forms of interaction

Myopridin potentiates the effect of anticholinergics such as atropine (see section 4.8).

4.6 Fertility, pregnancy and lactation

Pregnancy
This medicinal product is contraindicated in the first trimester of pregnancy.
During the further course of pregnancy, the medicinal product may only be used after a careful medical consideration, under medical supervision and only if absolutely necessary.

Breast-feeding
There are no data on the passage of pridinol intohuman milk.
Use during breastfeeding should be avoided.

Fertility
No data are available on the influence of pridinol on human fertility.

4.7 Effects on ability to drive and use machines

Due to potential anticholinergic effects on eyesight (see section 4.8), greater caution is advised when driving vehicles and operating machines.

4.8 Undesirable effects

Assessment of adverse effects is based on the following frequencies:

Very common	(≥ 1/10)
Common	(≥ 1/100, < 1/10)
Uncommon	(≥ 1/1000, < 1/100)
Rare	(≥ 1/10,000, < 1/1,000)
Very rare	(≥ 1/10,000)
Not known	(frequency cannot be estimated from the available data)

The frequency of adverse effects was estimated on the basis of a prospective, uncontrolled clinical study with 1,369 patients. With respect to case reports from the spontaneous reporting system, the frequency cannot be determined due to the lack of a real reference value. It is therefore included in the “not known” category “.
See the table below.

At the stated doses, adverse effects are rare to uncommon and generally disappear after a dose reduction or after discontinuation of the medicinal product.

The following adverse effects may occur, particularly during concomitant administration with other anticholinergic medicinal products Dry mouth, thirst, transient visual disorder (mydriasis, difficulties with accommodation, photosensitivity, slight increase in intraocular pressure), redness and dryness of the skin, bradycardia followed by tachycardia, micturition disorders, constipation and, very rarely, vomiting, dizziness and unsteady gait.

System organ class	**Uncommon**	**Rare**	**Not known**
Immune system disorders		Hypersensitivity (such as pruritus allergic, erythema, oedema mucosal, dyspnoea)	
Psychiatric disorders	Restlessness	Anxiety, depression	Hallucinations
Nervous system disorders	Dizziness, headache, speech disorder	Disturbance in attention, coordination abnormal, taste disorder	Tremor, paresthesia
Eye disorders		Accommodation disorder, visual impairment	Glaucomatocyclitic crises in angle closure glaucoma
Cardiac disorders	Tachycardia		Arrhythmia, bradycardia
Vascular disorders	Circulatory collapse, hypotension		
Gastrointestinal disorders	Nausea, abdominal pain, dry mouth	Diarrhea, vomiting	
Musculoskeletal and connective tissue disorders			Muscular weakness
Renal and urinary disorders			Micturition disorder, acute urinary retention in benign prostate hyperplasia
General disorders and administration site conditions	Fatigue, asthenia		Feeling hot

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

In the event of overdose or accidental poisoning, symptoms that are typical for anticholinergics occur.

When the severity of the symptoms requires it, intravenous physostigmine salicylate should be administered slowly.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
Muscle relaxants, centrally active agents; other centrally active agents
ATC code: M03BX03

The active substance of Myopridin is pridinol as pridinol mesilate, a piperidin-polyalcohol derivative with the chemical formula: 1,1-Diphenyl-1-ol-3-piperidin-propan-methanesulfonate.

Its pharmacological effect develops via an atropine-like mechanism that acts on both smooth and the striated muscles. This effect is used for the treatment of skeletal muscle tension of both central and peripheral origin.

Pridinol relieves muscle tensions more readily the early the myotonolytic treatment is started. In the cases of long-standing muscle spasms, where anatomical changes have also occurred in the muscle fibers, ligaments and joint capsules, Pridinol can only have a partial effect.

5.2 Pharmacokinetic properties

The kinetics of pridinol mesilate in humans have shown that, with oral administration, the maximum blood concentration is attained after about 1 hour and that there is a uniform distribution in the body. The active substance pridinol is largely excreted within 24 hours. This takes place via the kidneys, partly in unchanged form and partly as the glucoronate and as the sulfate-conjugate.

5.3 Preclinical safety data

Acute toxicity was investigated in studies on various animal species. The LD_{50} was 250 mg/kg in mice after oral administration, 446 mg/kg in rats after subcutaneous administration. In a chronic 6-month toxicity study in rats, no toxic effects were seen at doses of 5 to 20 mg/kg/day.
No teratogenic effects were observed in mice treated with a dose of 25 mg/kg/day pridinol mesilate.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Hydrogenated castor oil
Talc
Povidone K30
Colloidal silicon dioxide
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

PVC//Al blisters

Packs with 20, 50 and 100 tablets
Hospital packs with 200 (10 x 20), 500 (10 x 50) and 1000 (10 x 100) tablets
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

mibe pharma UK Ltd
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London, EC2R 5AR
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 49452/0010

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/05/2020

10 DATE OF REVISION OF THE TEXT

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