SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TRIMEVEL 150 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Trimebutine maleate .....150 mg

For a film-coated tablet.

Excipients with known effect: lactose monohydrate, sodium.
This medicine contains less than 1 mmol (23 mg) of sodium per tablet, that is to say it is essentially 'sodium free'.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

treatment of pain, transit disorders and intestinal discomfort related to functional bowel disorders.

4.2. Posology and method of administration

Oral route.

FOR ADULTS ONLY.
The usual dose is 1 tablet, 2 times a day and can exceptionally be increased to 2 tablets 2 times a day.
Treatment with TRIMEVEL 150 mg must be of duration.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Although this medication is intended for adults, it is important to remember that trimebutine is contraindicated in children under 2 years of age.

4.4. Special warnings and precautions for use

This medicine contains lactose (see section 2). Patients with galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption (rare hereditary disorders) should not take this medicine.

This medicine contains less than 1 mmol (23 mg) of sodium per tablet, that is to say it is essentially 'sodium free'.

4.5. Interactions with other medicinal products and other forms of interaction

Not applicable.

4.6. Pregnancy and breastfeeding

Pregnancy

Animal studies have not shown any teratogenic effects.
There is currently insufficient relevant data to assess a possible malformative or fetotoxic effect of trimebutine when administered during pregnancy.
Therefore, as a precautionary measure, it is best to avoid using trimebutine during the first trimester of pregnancy. In the absence of any expected adverse effects for the mother or child, the use of trimebutine during the second and third trimesters of pregnancy should only be considered if clearly necessary.

Breastfeeding

It is not known whether trimebutine passes into breast milk.
As a precaution, it is best to avoid using trimebutine while breastfeeding.

4.7. Effects on the ability to drive vehicles and use machinery

Not applicable.

4.8. Undesirable effects

The list of adverse effects below is derived from clinical trial experience and post-marketing data.

According to the organ system classification, adverse reactions are listed below in order of frequency using the following categories: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1000 to < 1/100); rare (≥ 1/10000 to < 1/1000); very rare (< 1/10000); not known (cannot be estimated from the available data).

Immune system disorders

Frequency not known: hypersensitivity reactions (pruritus, urticaria, angioedema and, exceptionally, anaphylactic shock)

Skin and subcutaneous tissue disorders

Uncommon: rash

Frequency not known: generalized maculopapular rash, erythema, eczematous reactions and exceptionally severe skin reactions including cases of acute generalized exanthematous pustulosis (AGEP), erythema multiforme, febrile drug eruption.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals report any adverse effects suspected unwanted substance via the FRILAB declaration form available under the tab Pharmacovigilance information from the website: www.frilab.ch

4.9. Overdose

In case of overdose, cardiac disturbances such as bradycardia, QTc interval prolongation, or tachycardia, and neurological disturbances such as drowsiness, seizures, and coma have been observed. Monitoring in a specialized setting is necessary, and symptomatic treatment should be implemented.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: MUSCULOTROPIC ANTISPASMODIC - ATC code: A03AA05.
(A: Digestive system and metabolism)
The effects of trimebutine are exerted at the level of the digestive tract on intestinal motility.
Trimebutine has enkephalinergic agonist properties. It stimulates intestinal motility by triggering propagated phase III waves of the migrating motor complex and inhibiting it upon prior stimulation (in animals).
In vitro, it acts by blocking sodium channels (IC50 = 8.4 µM) and inhibits the release of a mediator of nociception (glutamate).
In rats, it inhibits the animal's response to rectal and colonic distension in various experimental models.

5.2. Pharmacokinetic properties

Absorption

The maximum blood level of trimebutine after oral administration of tablets was obtained after 1 to 2 hours.

Elimination

The elimination of trimebutine after oral administration of tablets was mainly urinary and rapid: 70% on average within 24 hours.

5.3. Preclinical safety data

Repeated-dose toxicity studies of up to 6 months with oral trimebutine showed no adverse toxicological effects in rats and dogs. Genotoxicity studies (in vitro Ames test, chromosomal aberration test, and in vivo micronucleus test) showed no mutagenic or clastogenic effects of trimebutine. Trimebutine has no effect on the development and fertility of male and female rats. Reproductive and developmental studies with trimebutine showed no teratogenic effects in rats and rabbits. Carcinogenicity studies with trimebutine have not been conducted.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose monohydrate, pregelatinized maize starch, hypromellose, sodium carboxymethyl starch (type A), tartaric acid, anhydrous colloidal silica, magnesium stearate.

Film-coating: Hydroxypropylmethyl Cellulose (5 cps), titanium dioxide, talc, benzyl alcohol, propylene glycol, isopropyl alcohol, methylene chloride

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

Store at a temperature not exceeding 30°C.

6.5. Nature and contents of container

10 film-coated tablets in blister packs (PVC/Aluminium).

6.6. Special precautions for disposal and handling

No special requirements.

7. OPERATOR

FRILAB SA
17, rue des Pierres du Niton
1207 Geneva
SWISS

8. MANUFACTURER

Helios Pharmaceuticals Pvt. Ltd.
Village: Malpur, PO Bhud-1732205
Tehsil: Nalagarh, Dist: Solan, HP, India

9. DATE OF REVISION OF THE TEXT

October 2024

10. DOSIMETRY

Not applicable

CONDITIONS FOR PRESCRIPTION AND DISPENSING

List II