DEBRIDAT 100 mg, film-coated tablet

Trimebutine Maleate

Date: December 2021. Version n°7

Reference market: France

West Africa

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DEBRIDAT 100 mg, film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Trimebutine maleate.....100.00 mg

per film-coated tablet

Excipients with known effect: lactose, sodium

Each tablet contains 69.73 mg of lactose.

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

A list of excipients is provided in section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Symptomatic treatment: of pain, intestinal motility disorders and discomfort linked to intestinal function disorders.

4.2. Posology and method of administration

FOR ADULTS ONLY.

The usual starting dose is 1 tablet three times per day.

In exceptional cases, the dosage may be increased up to 6 tablets per day.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Although this medicinal product is only intended for adults, it should be noted that trimebutine is contraindicated in children under 2 years.

4.4. Special warnings and precautions for use

This medicinal product contains lactose (see section2). Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicine.

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

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

Not applicable.

4.6. Fertility, pregnancy and breastfeeding

Pregnancy

Studies in animals revealed no evidence of a teratogenic effect.

There are currently insufficient pertinent data to evaluate any deformative or foetotoxic effects of trimebutine when administered during pregnancy.

Consequently, as a precautionary measure, it is preferable not to use trimebutine during the first trimester of pregnancy. In the absence of any anticipated harmful effects for the mother or

child, the use of trimebutine during the 2nd and 3rd trimesters of pregnancy should not be considered unless necessary.

Breastfeeding

ItThe passage of trimebutine in breast milk is not known.

As a precaution, it is preferable to avoid taking trimebutine during breastfeeding.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

The list of undesirable effects below was derived from experience in clinical trials in adults, and from data reported post-marketing.

According to system organ class, undesirable side effects are listed below in order of frequency, and then by clinical importance 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, in rare cases, anaphylactic shock)

Skin and subcutaneous tissue disorders

Uncommon: skin rash

Frequency not known: generalized maculopapular rash, erythema, eczema reactions and, unusually, severe skin reactions including cases of acute generalized exanthematous pustulosis (AGEP), erythema multiforme and drug eruption with fever.

Reporting of suspected **side effects**

The reporting of suspected side effects 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 the national reporting system.

4.9. Overdose

In cases of overdose, cardiac disorders such as bradycardia, prolongation of the QTc interval, or tachycardia and neurological disorders such as drowsiness, convulsions and coma have been observed. A specialised monitoring environment is required, and symptomatic treatment will need to be implemented.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: **ANTISPASMODIC MUSCULOTROPIC**

ATC code: A03AA05

(A: **digestive** tract and metabolism)

The effects of trimebutine are exerted in the digestive tract on intestinal motility.

Trimebutine has enkephalinergic agonist properties. It stimulates intestinal motility by triggering phase III waves propagated by the migratory motor complex and by inhibiting it during preliminary stimulation (in animals).

In vitro, it acts by blocking sodium channels (IC50 = 8.4 µM) and inhibits the release of a nociception mediator (glutamate).

In rats, it inhibits the reaction of the animal to rectal and colonic distension in different 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 occurs primarily via the urine, and is rapid: 70% on average in 24 hours.

5.3. Preclinical safety data

Toxicity studies on trimebutine taken orally at repeated doses for up to 6 months have shown no adverse toxicological effects on rats and dogs. Genotoxicity studies (in vitro Ames test, chromosomal aberration and in vivo micronucleus test) have shown no mutagenic or clastogenic effects of trimebutine. Trimebutine has no effect on fertility development in male and female rats. Reproductive and developmental studies on trimebutine have shown no evidence of teratogenic effects in rats and rabbits. No carcinogenicity studies on trimebutine have been carried out.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

DEBRIDAT 100 mg, film-coated tablet

Lactose monohydrate, pregelatinized corn starch, hypromellose, sodium carboxymethyl starch, tartaric acid, anhydrous colloidal silica, magnesium stearate,

Film-coating: lactose monohydrate, hypromellose, macrogol 4000, titanium dioxide.

6.2. Incompatibilities

Not applicable.

6.3. Shelf-life

3 years.

6.4. Special precautions for storage

Store below 30°C

6.5. Nature and contents of the outer packaging

30 film-coated tablets in blisters (PVC / Aluminium).

6.6. Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURER

Holder:

PFIZER HOLDING FRANCE
23-25, AVENUE DU DOCTEUR LANNELONGUE
75014 PARIS
Manufacturer:

FARMEA

10, RUE BOUCHE THOMAS,

ZAC SUD D'ORGEMONT

49000 ANGERS

Presentations:
Debridat 100 mg, film-coated tablet. Box of 30 tablets in blister packs (PVC/Aluminium).

Local representative:
Pfizer West Africa

Administrative address:
Pfizer Afrique de l'Ouest
Regus Plateau 3rd Floor
Azur 15 Building
12 Boulevard Djily Mbaye
Dakar Sénégal BP 3857 Dakar RP

8. GENERAL CLASSIFICATION FOR SUPPLY

List II.

9. DATE OF REVISION OF TEXT

20 november 2020.