SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Norgalax

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 g micro-enema contains 120 mg of docusate sodium.

Excipient with known effect
Each 10 g micro-enema contains 3 g of glycerol (E 422).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Rectal gel.

Opalescent liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of constipation.

Preparation of the colon and rectum for endoscopic examination.

4.2 Posology and method of administration

Posology

Adults and children 12 years and over
Use one micro-enema. If required, a second micro-enema may be used on the same or the next day.

Paediatric population
Norgalax should not be used in children under 12 years old.

Method of administration
For rectal use.

Remove the protective cap and insert the applicator into the rectum, squeezing gently until the tube is empty. A drop of the gel maybe used as a lubricant if required.

4.3 Contraindications

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

Haemorrhoids, anal fissures, rectocolitis, anal bleeding, abdominal pain, intestinal obstruction, nausea, vomiting, inflammatory bowel disease, and ileus.

4.4 Special warnings and precautions for use

As with all laxatives, Norgalax should not be administered chronically. Prolonged use can precipitate the onset of an atonic non-functioning colon and hypokalaemia.

Norgalax contains glycerol (E 422). May have a mild laxative effect.

4.5 Interaction with other medicinal products and other forms of interaction

Norgalax may increase the resorption of medicines and is not to be used in combination with hepatotoxic agents.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate data from the use of docusate enema or oral docusate in pregnant women. Animal studies with oral docusate are insufficient with respect to effects on pregnancy and embryonic foetal development.
The potential risk for humans is unknown. As minimal systemic absorption cannot be ruled out following rectal application, Norgalax should be used in pregnancy only if the benefits outweigh the risks.

Breastfeeding
It is unknown whether docusate is excreted in human breast milk. Animal studies have shown excretion of docusate and its metabolites in breast milk when administered systemically. A decision on whether to continue/discontinue breast-feeding or continue/discontinue therapy with Norgalax should be made taking into account the benefit of breast-feeding to the child and the benefit of Norgalax therapy to the woman.

4.7 Effects on ability to drive and use machines

Norgalax has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Gastrointestinal disorders: anal burning, rectal pain, rectal bleeding, diarrhoea

Hepatobiliary disorders: cases of hepatotoxicity have been reported with oral intake of docusate taken together with other laxatives.

Skin and subcutaneous tissue disorders: urticaria

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 the 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

Overdose will lead to excessive purgation which should be treated symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for constipation, enemas, ATC code: A06AG10

Docusate sodium is an anionic surfactant and used as a faecal softening agent. It is considered to ease constipation by increasing the penetration of fluid into the faeces thereby causing them to soften. Norgalax is usually effective in 5 to 20 minutes.

5.2 Pharmacokinetic properties

Norgalax has a local effect in the rectum. Minimal absorption cannot be ruled out even with a rectal application.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of acute toxicity, repeated dose toxicity and in-vitro genotoxicity. Docusate sodium has been shown to exhibit developmental toxicity in rodents at oral doses that are maternally toxic and sufficiently in excess of the maximum human exposure indicating little relevance to clinical use. High oral doses given during lactation reduced pup weight and survival which was attributed to docusate and its metabolites present in the milk of the dams.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol (E 422)
Carmellose sodium
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

A LDPE tube with fixed LDPE applicator and a LDPE cap closure, containing 10 g of gel.

Pack sizes: 6 and 100 tubes.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Essential Pharma Limited
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UK.

8. MARKETING AUTHORISATION NUMBER(S)

PL 41871/0007

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 January 2005

10 DATE OF REVISION OF THE TEXT

19/09/2024