SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Norgalax

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Norgalax contains the active ingredient Docusate Sodium 0.12 g in each 10 g micro-enema.

3 PHARMACEUTICAL FORM

Rectal gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic treatment of constipation whenever an enema is required and for the preparation of the colon and rectum for endoscopic examination.

4.2 Posology and method of administration

***Adults*:** use one micro-enema. If required, a second micro-enema may be used on the same or the next day.

Children: not recommended for children under 12 years old.

Norgalax is to be administered rectally. Remove the protective cap and insert the applicator into the rectum, squeezing gently until the tube is empty. A drop of the gel may be used as a lubricant if required.

4.3 Contraindications

Haemorrhoids, anal fissures, rectocolitis, anal bleeding, abdominal pain, intestinal obstruction, nausea, vomiting, inflammatory bowel disease, ileus and known hypersensitivity to any of the ingredients.

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.

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.

Lactation

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

None known.

4.8 Undesirable effects

Gastrointestinal disorders: anal burning, rectal pain, rectal bleeding, diarrhoea
Skin disorders: urticaria
Hepatic disorders: cases of hepatotoxicity have been reported with oral intake of docusate taken together with other laxatives.

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 at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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
Sodium carboxymethyl cellulose

Purified Water

6.2 Incompatibilities

None known

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 polyethylene tube with fixed applicator and a cap closure, containing 10g of gel in pack sizes of 6 and 100 tubes.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

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