Midro® Tea

1 NAME OF THE MEDICINAL PRODUCT

Midro Tea

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Sennae folium (senna leaf).
For excipients, see 6.1.
1 g tea contains 750 mg senna leaves, corresponding to 19–21 mg hydroxyanthracene derivatives calculated as sennoside B.

3 PHARMACEUTICAL FORM

Tea

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Laxative

4.2 Posology and method of administration

Adults and children aged 12 years and older: take 0.5 to 1.5 g (e.g. to 1 measuring spoonfuls or to 1 sachet) in the evening, preferably 1 hour before bedtime, by chewing and/or swallowing with some water.
The daily dose may vary from one individual to another. Treatment should normally start with a small dose (e.g. measuring spoonful or sachet), which should be increased according to need. The maximum daily dose must not exceed 30 mg hydroxyanthracene derivatives, which corresponds to 1 measuring spoonfuls or 1 sachet. The correct individual dose is the smallest dose needed to obtain soft and well-formed stools.
The product may be taken only occasionally and for no longer than 1 to 2 weeks.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Diseases of the gastrointestinal tract (acute bowel inflammation, such as Crohn's disease and ulcerative colitis, strictures of the gastrointestinal system, intestinal obstruction or suspected appendicitis, abdominal pain of unknown origin); severe dehydration with fluid and electrolyte losses; hypersensitivity to the active substance or to any of the excipients according to the composition.
Children under 12 years.

4.4 Special warnings and precautions for use

The long-term use of laxatives must be avoided. Abuse with subsequent loss of fluid and electrolytes can have undesirable consequences such as: dependence, possibly accompanied by the need to increase the dose, fluid and electrolyte imbalance (mainly hypokalaemia), as well as colonic atony with functional restriction
In the event of permanent use, medical surveillance is required.

4.5 Interaction with other medicinal products and other forms of interaction

As hypokalaemia is possible, interactions can be expected with digitalis glycosides, type I antiarrhythmic agents and certain antihistamines such as terfenadine.
Concomitant use of other medications that may cause hypokalaemia (such as diuretics, corticosteroids, liquorice) will aggravate hypokalaemia.

4.6 Pregnancy and lactation

No harmful effects on the foetus have been reported to date when the recommended dosages were observed during pregnancy. Nevertheless, based on experimental data on the genotoxicity of various anthranoids, ingestion of Midro Tea during pregnancy is not recommended. Midro Tea is not recommended for use during breastfeeding, as there are insufficient data on the passage of metabolites into human milk.

4.7 Effects on ability to drive and use machines

The effect of this medicinal product on the ability to drive and use machines has not been studied; however, this is unlikely.

4.8 Undesirable effects

In a few cases: bloating, cramp-like gastrointestinal disturbances or diarrhoea. A dose reduction is required in such cases. Yellow or brown discolouration of the urine (depending on pH) due to metabolites. Such discolouration is not clinically relevant.
Diarrhoea may occur at high doses or with prolonged or frequent use, with fluid and electrolyte losses (particularly loss of potassium), albuminuria and haematuria, as well as pigmentation of the intestinal mucosa (pseudomelanosis coli). However, the latter is mild and usually resolves upon discontinuation of the product.

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.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.9 Overdose

Severe diarrhoea can occur in cases of acute overdose, with intestinal irritation and spasms, as well as significant electrolyte loss. Therapeutic measures consist of administering absorbents and restoring the fluid and electrolyte balance. In the presence of gastric colic, administer antispasmodic agents if necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: A06AB56
Senna belongs to the group of stimulating laxatives of the anthracene type. The active products extracted from senna leaves – sennosides – are anthraquinone glycosides, which become effective only after enzymatic transformation in the colon. The effect is based on active secretion of electrolytes and water in the intestinal lumen. At the same time, absorption of electrolytes and water through the colon is restricted. The result is a softening of the intestinal contents and an increase in their volume, which increases the filling pressure in the intestine and ultimately stimulates and accelerates peristaltic movement. Defecation takes place 8–12 hours later.

5.2 Pharmacokinetic properties

Glycosides with a beta-glycosidic bond (sennosides) are active prodrugs, which are neither cleaved nor absorbed in the upper gastrointestinal tract. They are degraded to rhein anthrone in the colon by the action of bacterial enzymes. Rhein anthrone is the metabolite with a laxative effect. The systemic availability of rhein anthrone is very low. Animal experiments using radioactive rhein anthrone directly applied to the caecum have shown that absorption is <10%. Oxygen oxidises rhein anthrone to rhein and sennidins, which are recovered in the blood as glucuronides and sulphates.

5.3 Preclinical safety data

After oral administration of sennosides in rats and guinea pigs, no embryotoxic or foetotoxic reaction has been observed. Furthermore, there was no influence on the postnatal development of neonates, maternal behaviour or the fertility of male and female rats. No data are available on the herbal preparation.

A senna extract, as well as aloe emodin, were shown to be mutagenic *in vitro*. Conversely, sennosides A and B, as well as rhein, yielded negative results. *In vivo* mutagenicity studies on a senna fruit extract proved negative.
The active metabolites, such as rhein, pass into human milk in small quantities. No laxative effect has been observed in breast-fed infants. In animal experiments, passage through the placental barrier is extremely low for rhein.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

CARAWAY FRUIT, PEPPERMINT LEAF, LIQUORICE ROOT, COMMON MALLOW FLOWERS, LARKSPUR FLOWERS.

6.2 Shelf life

The expiry date of the product is indicated on the packaging materials

6.3 Storage

Do not store above 25°C. Protect from light.
Keep Midro Tea out of the reach of children.

6.4 Nature and contents of container

Midro Tea 80 g. (B)

7 REGISTRATION NUMBER

130-27-20919-00

8 REGISTRATION HOLDER

Neopharm (Israel)1996 Ltd.,
P.O.Box 7063, Petach Tiqva 49170

9 MANUFACTURER

Midro AG Richen, Switzerland
revised in June 2022 according to MOH guidelines