SCHEDULING STATUS

S0

PROPRIETARY NAME AND DOSAGE FORM

Black Forest® Herbal Tea (Decoction)

COMPOSITION

Each 2,5 g tea contains:
Senna leaf 1,1125 g equivalent to 27,81 mg sennoside B.
Sugar free.

PHARMACOLOGICAL CLASSIFICATION

A 11.5 Laxatives.

PHARMACOLOGICAL ACTION

It promotes bowel movement by one or more direct actions on the intestines.

INDICATIONS

For the relief of occasional constipation.

CONTRAINDICATIONS

Hypersensitivity or allergy to Senna leaves.
Intestinal obstruction or undiagnosed abdominal symptoms.
Not to be used by pregnant and lactating females.

WARNINGS AND SPECIAL PRECAUTIONS

This medicine should not be used in the presence of abdominal pain, nausea, or vomiting. Care should also be taken in patients with inflammatory bowel disease. Do not use for longer than 1 week, except on the advice of a doctor. Frequent or prolonged use of this preparation may result in dependence on laxatives and loss of normal bowel function. If you have noticed a sudden change in bowel habits that has persisted for a period of greater than 2 weeks, consult a doctor before using the laxative. Rectal bleeding or failure to have bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult a doctor.

PREGNANCY & LACTATION

Not to be used by pregnant and lactating females.

DOSAGE AND DIRECTIONS FOR USE

Adults and children 12 years and over
One tea bag to a cup of boiling water every night, or less frequently as required. Allow the tea to steep for 5 minutes before drinking. If required, milk, sugar, sweetener, a slice of lemon, etc. can be added to taste.

Children 6 to 12 years
Half of the adult dosage. Use half a cup of above-mentioned tea every night, or less frequently as required.
Not recommended for use in children under the age of 2 years.

SIDE-EFFECTS

Senna may cause abdominal discomfort such as colic or cramps.
The prolonged use or overdosage may result in diarrhoea, excessive loss of water and electrolytes, particularly potassium and possible atonic non-functioning colon.
Discolouration of urine may occur and may interfere with diagnostic tests.
Cardiac and renal symptoms have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See side effects and special precautions.
Treatment is symptomatic and supportive.

IDENTIFICATION

Tea bag, filled with broken-up dried leaves, brownish green in colour, with an aromatic odour.

PRESENTATION

Pillow foil containing ten or twenty 2,5 g tea bags, in a unit carton.

STORAGE INSTRUCTIONS

Protect from light and store in an airtight container below 25 °C.
Keep out of the reach of children.

REGISTRATION NUMBER

E/11.5/1036.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Nativa (Pty) Ltd
260 Cradock Avenue,
Lyttelton, Centurion, 0157,
Gauteng, South Africa.

DATE OF PUBLICATION OF THIS PACKAGE INSERT

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SKEDULERINGSTATUS
S0

EIENDOMSNAAM EN DOSEERVORM
Black Forest® Herbal Tea (Brousel)

SAMESTELLING
Elke 2,5 g tee bevat:
Sennablaar 1,1125 g ekwivalent aan 27,81 mg sennosiede B.
Suikervry.

FARMAKOLOGIESE KLASSIFIKASIE
A 11.5 Lakseermiddels.

FARMAKOLOGIESE WERKING
Bevorder dermbeweging deur een of meer direkte uitwerking op die derms.

INDIKASIES
Vir die verligting van ongereelde hardlywigheid.

KONTRA-INDIKASIES
Hipersensitiwiteit of allergie vir Sennablare.
Intestinale obstruksie of ongediagnoseerde abdominale simptome.
Moet nie deur swanger of lakterende vrouens gebruik word nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Hierdie medisyne moet nie gebruik word indien daar abdominale pyn, naarheid of braking teenwoordig is nie. Sorg moet gedra word by pasiënte met inflammatoriese ingewandsiekte. Moet nie vir langer as 1 week gebruik, tensy op aanbeveling van 'n geneesheer nie. Gereelde of langdurige gebruik van hierdie preparaat kan tot afhanklikheid van lakseermiddels en verlies van normale dermfunksie lei. Indien u 'n skielike verandering in stoelgang gereeldheid opmerk wat vir langer as 2 weke aanhou, moet 'n geneesheer geraadpleeg word alvorens die lakseermiddel gebruik word. Rektale bloeding of mislukking om dermbeweging te kry na gebruik van 'n lakseermiddel kan dui op 'n ernstige toestand. Staak gebruik en raadpleeg 'n geneesheer.

SWANGERSKAP EN LAKTASIE
Moet nie gebruik word deur swanger vroue en vroue wat borsvoed nie.

DOSIS EN GEBRUIKSAANWYSINGS
Volwassenes en kinders 12 jaar en ouer
Een teesakkie in 'n koppie kokende water elke aand, of minder dikwels, soos nodig. Laat die tee vir 5 minute trek voordat dit gedrink word. Indien verkies, kan melk, suiker, 'n versoeter, 'n skyfie suurlemoen ens. na smaak bygevoeg word.

Kinders 6 tot 12 jaar
Helfte van die volwasse dosis. Gebruik 'n halwe koppie van bogenoemde tee, of minder dikwels, soos nodig.
Nie aanbeveel vir kinders onder die ouderdom van 2 jaar nie.

NEWE-EFFEKTE
Senna kan abdominale ongemak soos koliek of krampe veroorsaak.
Langdurige gebruik of oordosering kan lei tot diarree, oormatige verlies van water en elektroliete, veral kalium en die moontlikheid van 'n atoniese nie-funksionerende kolon.
Verkleuring van uriene kan voorkom en kan inmeng met diagnostiese toetse.
Hart en niersimptome is al vermeld.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Verwys na newe-effekte en spesiale voorsorgmaatreëls.
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE
Teesakkie met gebreekte droë blare, bruingroen van kleur, met 'n aromatiese geur.

AANBIEDING
Foeliesakkie met tien of twintig 2,5 g teesakkies, in 'n kartonhouer.

BERGINGSAANWYSINGS
Beskerm teen lig en bewaar in 'n lugdigte houer onder 25 °C.
Hou buite die bereik van kinders.

REGISTRASIENOMMER
E/11.5/1036.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE
Nativa (Edms) Bpk
Cradocklaan 260,
Lyttelton, Centurion, 0157,
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