PATIENT INFORMATION LEAFLET

BLACK FOREST® HERBAL TEA (DECOCTION)

SCHEDULING STATUS
S0

BLACK FOREST® HERBAL TEA (decoction)
Sennoside B - 27,81 mg
Sugar free

Read all of this leaflet carefully before you start taking BLACK FOREST® HERBAL TEA because it contains important information for you.

BLACK FOREST® HERBAL TEA is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use BLACK FOREST® HERBAL TEA carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BLACK FOREST® HERBAL TEA with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

WHAT IS IN THIS LEAFLET
1. What BLACK FOREST® HERBAL TEA is and what is it used for
2. What you need to know before you take BLACK FOREST® HERBAL TEA
3. How to use BLACK FOREST® HERBAL TEA
4. Possible side effects
5. How to store BLACK FOREST® HERBAL TEA
6. Contents of the pack and other information

1. What BLACK FOREST® HERBAL TEA is and what is it used for

BLACK FOREST® HERBAL TEA contains Senna leaf and is a laxative used for short term relief of occasional constipation. This tea does not help with weight loss.

2. What you need to know before you take BLACK FOREST® HERBAL TEA

Do not take BLACK FOREST® HERBAL TEA if you:

- are hypersensitive (allergic) to Senna or any of the ingredients (for a full list of ingredients, see section **6. What BLACK FOREST® HERBAL TEA contains**);
- have persistent or undiagnosed abdominal discomfort e.g. pain, nausea and vomiting;
- have appendicitis (sharp pain in lower right abdomen);
- swelling and pain in the bowel accompanied with diarrhoea or loose stools as in inflammatory bowel disease e.g. Crohn's disease or ulcerative colitis;
- have faecal impaction (when stools become hard and dry and are difficult to pass and cause blockage) or rectal bleeding or blood in your stools for which you do not know the cause;
- have already taken a laxative and are still constipated;
- have blockage, narrowing or paralysis of the digestive tract or bowel (ileus, intestinal obstruction or stenosis);
- have severe dehydration – symptoms include thirst, feeling faint, and having headaches. It can also mean you cannot pass enough urine;
- have a sudden change in bowel habit that has lasted for more than 2 weeks;
- have kidney or heart failure;
- are pregnant.

Warnings and precautions
Tell your doctor, pharmacist or healthcare practitioner if you have one (1) or more of the following:

- If you suffer from kidney disorders;
- If you are not satisfied or your symptoms do not improve within one (1) week or if symptoms worsen or persist;
- If you are suffering from severe diarrhoea which may result in severe water and electrolyte loss, particularly potassium;
- If you are taking medicines for a heart condition such as irregular heart-beat, (e.g. cardiac glycosides, antiarrhythmic medicines e.g. quinidine), diuretics (used to increase excretion of urine), adrenocorticoids such as cortisone or steroidal medicines, as low potassium levels (resulting from long term laxative abuse) may cause interference;
- If you have rectal bleeding or failure to have bowel movement after use - this may indicate a serious condition;
- If you need to take laxatives every day;
- If you have persistent abdominal pain.

Take special care with BLACK FOREST® HERBAL TEA
- If you are unable to have a bowel movement after using BLACK FOREST® HERBAL TEA, discontinue use and consult your doctor;
- Laxatives should not be used for prolonged periods as they may cause loss of normal bowel function and dependence on laxatives;
- When giving this product to incontinent adults, pads should be changed more frequently to prevent extended skin contact with faeces.

Taking other medicines with BLACK FOREST® HERBAL TEA
- Always tell your doctor or healthcare professional if you are taking other medicines on a regular basis, including complementary or traditional medicines. Please consult your doctor, pharmacist or other healthcare professional for advice;
- Low potassium levels (resulting from long term laxative abuse) may cause interference with medicines for heart condition such as irregular heartbeat, (e.g. cardiac glycosides, antiarrhythmic medicines e.g. quinidine), diuretics (used to increase excretion of urine), adrenocorticoids such as cortisone or steroidal medicines;
- Absorption of other medicines, taken at the same time, may be decreased or slowed down.

Taking BLACK FOREST® HERBAL TEA with food and drink
- It is recommended to make changes in your diet and use bulk forming agents to control constipation before using this medicine.

Pregnancy and Breastfeeding
- You should not use BLACK FOREST® HERBAL TEA if you are pregnant or breast-feeding;
- If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor or pharmacist or other health care provider for advice before taking this medicine.

Driving and using machinery
No research studies have been conducted on the effect on the ability to drive or handle machinery. BLACK FOREST® HERBAL TEA is unlikely to affect the ability to drive or use machinery. However, be careful until you are sure your ability to perform these activities are not affected.

Porphyria
Safety has not been established.

3. How to use BLACK FOREST® HERBAL TEA

Do not share medicines prescribed for you with any other person.
Always take BLACK FOREST® HERBAL TEA exactly as described in this leaflet or as your health-care provider has instructed you. Check with your health care provider if you are unsure.

How to make BLACK FOREST® HERBAL TEA?
Place one tea bag or 5 ml medicine measure of loose tea in a cup of boiling water. Allow the tea to steep for 3 - 5 minutes before drinking. If required, milk, sugar, sweetener, a slice of lemon, honey, etc. can be added to improve taste.

How much and how often should you use BLACK FOREST® HERBAL TEA?

Adults and children 12 years and over:
Take one cup of tea, made as above at bedtime.

Children 6 to 12 years
Take half a cup of tea, made as above at bedtime.

Not recommended for use in children under the age of 2 years.

Duration of use:
Normally it is sufficient to take this medicinal product up to two to three times a week. Use for more than 1 to 2 weeks requires medical supervision.

If you take more BLACK FOREST® HERBAL TEA than you should:

- In the event of over-dosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre;
- You may experience painful intestinal cramps and severe diarrhoea with subsequent loss of water and minerals;
- Replacement of fluids and correction of electrolyte imbalance may be required. This is especially important in the elderly and the young.

If you forget to take / missed a dose of BLACK FOREST® HERBAL TEA
Take your missed dose when you remember. Do not take a double dose to make up for forgotten individual doses.

If you stop taking BLACK FOREST® HERBAL TEA
After taking too much of this medicine for too long and suddenly stop, may lead to a lazy bowel, where the muscle in the bowel becomes too relaxed. This can lead to long-term constipation.

4. Possible side effects

BLACK FOREST® HERBAL TEA can have side effects.
Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, or if you experience any untoward effects while taking BLACK FOREST® HERBAL TEA, please consult your healthcare provider for advice.

Like all medicines, this medicine can cause side effects although not everybody gets them.

If any of the following or other side effects occur, stop taking this product and consult your doctor or pharmacist or go to the casualty department at your nearest hospital:

- allergic reactions such as local or more widespread skin rashes, hives (skin bumps), local itchiness, swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- low levels of potassium in the blood (called 'hypokalaemia'). This can make you tired, dizzy, make your muscles weak and cause an uneven heartbeat.

Tell your doctor or pharmacist if you notice any of the following side effects, the frequency of which is not known:
- chronic use may cause pigmentation of the gastrointestinal tract which usually recedes when the product is no longer taken;
- chronic use may lead to albuminuria and haematuria which is albumin or blood in the urine;
- yellow or red-brown discolouration of urine may occur during the treatment, but is harmless although this may interfere with diagnostic tests;
- abdominal pain, spasms, colic, cramps and diarrhoea, in particular in patients with irritable colon;
- changes in the shape of the finger and fingernail, muscular spasms and inflammation of the bones and joints.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist, nurse or other healthcare practitioner for advice. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BLACK FOREST® HERBAL TEA

5. How to store BLACK FOREST® HERBAL TEA
- Store all medicines out of reach of children;
- Store at or below 25 °C;
- Protect from light and moisture;
- Store in original packaging until required for use;
- Keep the foil pillow in the unit carton;
- Do not store in a bathroom;
- Do not use after the expiry date stated on the package;
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What BLACK FOREST® HERBAL TEA contains

- The active substance per 2,5 g of tea leaves is:
  1,1125 g of Senna Leaf equivalent to 27,81 mg Sennoside B;
- The other ingredients are Cinnamon leaf oil, Ethanol, Fennel seeds, fol. Uva Ursi (Bearberry leaf), fol. Yerba Mate, Lemon oil, Lemon oil terpeneless, Peppermint oil and Valerian root;
- This tea is sugar free.

What BLACK FOREST® HERBAL TEA looks like and contents of the pack

BLACK FOREST® HERBAL TEA is presented as broken-up dried leaves, brownish green in colour, with an aromatic odour, available as a loose tea or in tea bags as follows:
(i) Cartons and/or foil pillow containing 25 g or 50 g loose tea, as well as a patient information leaflet;
(ii) Cartons and/or with foil pillow containing ten or twenty 2,5 g tea bags, as well as a patient information leaflet.

Holder of Certificate of Registration

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Professional Information
The BLACK FOREST® HERBAL TEA Professional Information may be obtained from the Nativa website (www.nativa.co.za)

Botswana Reg. No. : B9302630 Schedule 4

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PPAT038/01

PASIËNTINLIGTINGSBROSJURE

BLACK FOREST® HERBAL TEA (DECOCTION)

SKEDULERINGSTATUS
S0

BLACK FOREST® HERBAL TEA (decoction)
Sennosied B - 27,81 mg
Suikervry

Lees hierdie hele voubiljet noukeurig deur voor u begin om BLACK FOREST® HERBAL TEA te neem want dit bevat belangrike inligting vir jou.

BLACK FOREST® HERBAL TEA is beskikbaar sonder 'n doktersvoorskrif sodat jy 'n ligte siekte kan behandel. Nogtans moet jy BLACK FOREST® HERBAL TEA versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie voubiljet. Jy sal dit dalk later weer moet lees.
- Moenie BLACK FOREST® HERBAL TEA met enigiemand anders deel nie.
- Vra jou gesondheidsorgverskaffer of apteker indien jy meer inligting of advies nodig het.
- Jy moet 'n dokter gaan spreek indien jou simptome vererger of ná 7 dae nie verbeter nie.

WAT IS IN HIERDIE VOUBILJET
1. Wat BLACK FOREST® HERBAL TEA is en waarvoor dit gebruik word
2. Wat u moet weet voordat u BLACK FOREST® HERBAL TEA drink
3. Hoe om BLACK FOREST® HERBAL TEA te gebruik
4. Moontlike newe-effekte
5. Hoe om BLACK FOREST® HERBAL TEA te bewaar
6. Inhoud van die pak en ander inligting

1. Wat BLACK FOREST® HERBAL TEA is en waarvoor dit gebruik word

BLACK FOREST® HERBAL TEA bevat sennablare en is 'n lakseermiddel vir korttermynverligting van hardlywigheid wat soms voorkom. Hierdie tee help nie met gewigsverlies nie.

2. Wat u moet weet voordat u BLACK FOREST® HERBAL TEA drink

Moenie BLACK FOREST® HERBAL TEA neem indien jy:

- allergies (hipersensitief) is vir senna of enige van die bestanddele (vir 'n volle lys bestanddele, sien afdeling **6. Wat BLACK FOREST® HERBAL TEA bevat**);
- aanhoudende of ongediagnoseerde buikongemak, bv. pyn, naarheid en braking, het;
- blindedermontsteking (steekpyn in die laer regterkant van die buik) het;
- swelling en pyn in die derm het wat gepaart gaan met diarree of los stoelgange soos in inflammatoriese dermkanaalsiekte, bv. Crohn se siekte of ulseratiewe kolitis;
- fekale impaksie het (wanneer stoelgange hard en droog word en moeilik is om uit te werp en verstopping veroorsaak) of rektale bloeding of bloed in jou stoelgange waarvan jy nie weet wat die oorsaak is nie;
- reeds 'n lakseermiddel geneem het en steeds hardlywig is;
- verstopping, vernouing of verlamming van die spysverteringskanaal of derm (ileus, intestinale obstruksie of stenose) het;
- erge dehidrasie het – simptome sluit in: dors, flou gevoel en hoofpyne. dit kan ook beteken dat u nie genoeg urine passeer nie;
- 'n skielike verandering in ingewandsgewoontes het wat al meer as 2 weke duur;
- nier- of hartversaking het;
- swanger is.

Waarskuwings en voorsorgmaatreëls
Sê vir jou dokter, apteker of gesondheidsorgverskaffer as jy een (1) of meer van die volgende het:

- Indien jy aan erge niervversteurings ly;
- Indien jy nie tevrede is nie of indien jou simptome nie binne een (1) week verbeter nie of indien simptome vererger of voortduur;
- Indien jy erge diarree het wat tot erge verlies van water en elektroliete kan lei, veral kalium;
- Indien jy medisyne neem vir 'n harttoestand soos onreëlmatige hartklop (bv. kardiale glikosiede, anti-aritmiese middels, bv. kinidien), diuretikums (wat gebruik word om die uitskeiding van urien te vermeerder), adrenokortikoïede soos kortisoon of steroïdale medisyne, aangesien lae kaliumvlakke (wat as gevolg van langtermynlakseermiddelmisbruik kan wees) versteuring kan veroorsaak;
- Indien jy rektale bloeding het of nie opelyf het ná gebruik nie – dit kan 'n ernstige toestand aandui;
- Indien jy elke dag lakseermiddels moet neem;
- Indien jy voortdurend buikpyn het.

Wees versigtig met BLACK FOREST® HERBAL TEA

- Indien jy nie 'n stoelgang kan hê nadat jy BLACK FOREST® HERBAL TEA gebruik nie, staak gebruik en raadpleeg jou dokter;
- Lakseermiddels moet nie oor lang tye gebruik word nie aangesien dit moontlik 'n verlies van normale dermfunksie en afhanklikheid aan lakseermiddels kan veroorsaak;
- Wanneer hierdie produk aan inkontinente volwassenes gegee word, moet doekies meer dikwels geruil word om verlengde blootstelling van die vel aan ontlasting te vermy.

Gebruik van ander medisyne saam met BLACK FOREST® HERBAL TEA
- Vertel jou dokter of gesondheidsorgkundige altyd as jy enige ander medisyne neem op gereelde basis, insluitende aanvullende of tradisionele medisyne. Raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgkundige vir raad;
- Lae kaliumvlakke (wat veroorsaak word deur langtermynlakseermiddelmisbruik) kan inmenging veroorsaak met medisyne vir 'n harttoestand soos onreëlmatige hartklop (bv. kardiale glikosiede, anti-aritmiese middels, bv. kinidien), diuretikums (wat gebruik word om die uitskeiding van uriene te vermeerder), adrenokortikoïede soos kortisoon of steroïdale medisyne;
- Opname van ander medisyne wat terselfdertyd geneem word, kan verminder of vertraag word.

Gebruik BLACK FOREST® HERBAL TEA met kos en drank
- Daar word aanbeveel dat jy veranderinge in dieët maak en massavormende middels gebruik om hardlywigheid te beheer voordat jy hierdie medisyne gebruik.

Swangerskap en borsvoeding
- Jy moet nie BLACK FOREST® HERBAL TEA gebruik indien jy swanger is of borsvoed nie;
- As jy swanger is of borsvoed, dink dat jy swanger is of beplan om 'n baba te hê, raadpleeg asseblief jou dokter of apteker of ander gesondheidsorgverskaffer vir raad voordat jy hierdie medisyne neem.

Effek op die vermoë om motor te bestuur en masjinerie te gebruik
Geen navorsingstudies is uitgevoer oor die effek op die vermoë om te bestuur of masjinerie te hanteer nie. Dit is onwaarskynlik dat BLACK FOREST® HERBAL TEA die vermoë om te bestuur of masjinerie te gebruik sal beïnvloed. Wees egter versigtig tot u seker is u vermoë om hierdie aktiwiteite uit te voer word nie beïnvloed nie.

Porfirie
Veiligheid is nog nie vasgestel nie.

3. Hoe om BLACK FOREST® HERBAL TEA te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enigiemand anders deel nie.
Neem altyd BLACK FOREST® HERBAL TEA presies soos in hierdie voubiljet beskryf word of soos jou gesondheidsorgverskaffer jou aangewys het. Maak seker by jou gesondheidsorgverskaffer indien jy onseker is.

Hoe maak 'n mens BLACK FOREST® HERBAL TEA?
Plaas een teesakkie of 'n 5 ml-medisynemaat los tee in 'n koppie kookwater. Laat dit 3 - 5 minute trek voor dit gedrink word. Indien nodig kan melk, suiker, versoeter, 'n skyfie suurlemoen, heuning, ens., bygevoeg word na smaak.

Hoeveel en hoe dikwels moet jy BLACK FOREST® HERBAL TEA gebruik?

Volwassenes en kinders van 12 jaar en ouer:
Neem een koppie tee met slaaptyd, voorberei soos hierbo.

Kinders 6 tot 12 jaar
Gee 'n kwart koppie tee met slaaptyd, voorberei soos hierbo.

Nie aanbeveel vir kinders onder die ouderdom van 2 jaar nie.

Duur van gebruik:
Normaalweg behoort dit genoeg te wees om hierdie medisinale produk twee tot drie keer per week te neem. Gebruik vir meer as 1 tot 2 weke vereis mediese toesig.

Indien jy meer BLACK FOREST® HERBAL TEA gebruik as wat jy moet:

- In geval van oordosering, raadpleeg jou dokter of apteker. Indien geeneen beskikbaar is nie, kry hulp by die naaste hospitaal of gifbeheersentrum;
- Jy kan moontlik pynlike dermkrampe en erge diarree ondervind met daaropvolgende verlies van water en minerale;
- Vloeistofvervanging en balansering van elektrolietvlakke mag nodig wees;
- Dit is veral belangrik by bejaardes en jong persone.

Indien jy vergeet/nagelaat het om 'n dosis BLACK FOREST® HERBAL TEA te neem
Neem die oorgeslane dosis sodra jy daarvan onthou. Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat jy oorgeslaan het nie.

Wanneer u ophou om BLACK FOREST® HERBAL TEA te neem
Nadat u te veel van die medisyne vir te lank gebruik het en skielik opgehou het, kan dit lei tot 'n lui derm, waar die spier in die derm te ontspanne raak. Dit kan tot langdurige hardlywigheid lei.

4. Moontlike newe-effekte

BLACK FOREST® HERBAL TEA kan newe-effekte hê.
Nie alle newe-effekte wat vir BLACK FOREST® HERBAL TEA gerapporteer word, word in hierdie bylae ingesluit nie. Indien u algemene gesondheid vererger of u enige onvoorsiene effekte ondervind wanneer u hierdie medisyne gebruik, raadpleeg u gesondheidsorgverskaffer vir advies.

Soos alle medisyne, kan hierdie medisyne newe-effekte veroorsaak, alhoewel nie almal dit ervaar nie.

Indien enige van die volgende of ander newe-effekte voorkom, hou op om hierdie produk te neem en raadpleeg jou dokter of apteker of gaan na die ongevalle-afdeling in u naaste hospitaal

- allergiese reaksies soos lokale of meer verspreide veluitslag, galbulte (velbulte), lokale jeukerigheid, swelling van die gesig, lippe, mond of keel, wat probleme met sluk of asemhaling kan veroorsaak;
- lae kaliumvlakke in die bloed (wat hipokalemie genoem word). Dit kan jou moeg en duiselig laat voel asook jou spiere swak maak en 'n onreëlmatige hartklop veroorsaak.

Sê vir jou dokter indien jy enige van die volgende newe-effekte oplet, waarvan die frekwensie onbekend is:

- chroniese gebruik kan pigmentasie van die spysverteringskanaal veroorsaak wat gewoonlik verminder wanneer die produk nie meer geneem word nie;
- chroniese gebruik kan tot albuminurie en hematurie lei, wat albumien of bloed in die urien is;
- geel of rooibruin verkleuring van uriene kan gedurende die behandeling plaasvind, maar is onskadelik al kan dit met diagnostiese toetse inmeng;
- buikpyn, spasmas, koliek, krampe en diarree, in die besonder by pasiënte met prikkelbare kolon;
- veranderinge in die vorm vir die vinger en vingernael, spierspasmas en inflammasie van die beendere en gewrigte.

As jy enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie, stel asseblief jou dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien jy newe-effekte ondervind, vra jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer vir raad. Jy kan ook newe-effekte by SAHPRA aanmeld via die aanmeldingsvorm vir ongewenste reaksie op middels "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn onder SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van BLACK FOREST® HERBAL TEA te voorsien.

5. Hoe om BLACK FOREST® HERBAL TEA te bewaar

- Bewaar alle medisyne buite bereik van kinders;
- Bewaar teen of onder 25 °C;
- Beskerm teen lig en vog;
- Bewaar in die oorspronklike verpakking tot voor gebruik;
- Hou die foeliesakkie in die eenheidskarton;
- Moet nie in 'n badkamer bêre nie;
- Moet nie gebruik ná die vervaldatum wat op die verpakking verskyn nie;
- Neem alle ongebruikte medisyne terug na jou apteker;
- Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting
Wat BLACK FOREST® HERBAL TEA bevat

- Die aktiewe bestandeel per 2,5 g teeblare is:
  1,1125 g Sennablaar gelyk aan 27,81 mg Sennosied B;
- Die ander bestanddele is Etanol, fol. Uva Ursi, fol. Yerba Mate, Kaneelblaarolie, Pepermentolie, Suurlemoenolie, Terpeenlose Suurlemoenolie, Valeriaanwortel;
- Hierdie tee is suikervry.

Hoe BLACK FOREST® HERBAL TEA lyk en inhoud van die pakkie

BLACK FOREST® HERBAL TEA word aangebied as opgebreekte, gedroogde blare, bruingroen in kleur, met 'n geurige aroma, beskikbaar as los tee of in teesakkies soos volg:
(i) Kartonne en/of foeliesakkies met 25 g of 50 g los tee, sowel as 'n pasiëntinligtingsbrosjure;
(ii) Kartonne en/of foeliesakkes wat tien of twintig 2,5 g-teesakkies bevat, sowel as 'n pasiëntinligtingsbrosjure.

Houer van registrasiesertifikaat

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Hierdie voubiljet is laas hersien in:
Desember 2019

Datum van registrasie
08 Desember 1995

Registrasienommer
Suid-Afrikaanse Reg. No.: E/11.5/1036

Professionele inligting
Die BLACK FOREST® HERBAL TEA professionele inligting kan van die Nativa-webwerf (www.nativa.co.za) verkry word

Botswana Reg. No.: B9302630 Schedule 4

Namibia Reg. No.: 04/11.5/0332 Schedule 0

® Geregistreede Handelsmerk

PPAT038/01