PATIENT INFORMATION LEAFLET

Enterogermina®

2 billion/5 ml, oral suspension
Sugar free

SCHEDULING STATUS

S0

CATEGORY AND CLASS

Class D: Complementary Medicines:
Health supplement; 34.9 Probiotics

PROPRIETARY NAME AND DOSAGE FORM
ENTEROGERMINA 2 billion (oral suspension)

Each 5 ml vial contains 2 billion polyantibiotic-resistant *Bacillus clausii* spores (strains SIN, O/C, T, N/R).
Sugar Free

Excipients:

Purified water

Read all of this leaflet carefully because it contains important information for you.

ENTEROGERMINA 2 billion suspension is available without a doctor's prescription for you to maintain your health.
Nevertheless, you still need to take ENTEROGERMINA 2 billion suspension carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ENTEROGERMINA 2 billion suspension with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What ENTEROGERMINA 2 billion suspension is and what it is used for.
2. What you need to know before you take ENTEROGERMINA 2 billion suspension
   a. Contra-indications
   b. Warnings and precautions
   c. Possible side effects.
   d. Interactions
3. How to take ENTEROGERMINA 2 billion suspension
4. How to store ENTEROGERMINA 2 billion suspension
5. Description of contents of the pack and container information.

1. What ENTEROGERMINA 2 billion suspension is and what it is used for.

ENTEROGERMINA 2 billion suspension is a Health supplement, probiotic. When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract.

Probiotics assist to restore the intestinal microbial flora, altered during the use of antibiotics.
Supportive supplement during antibiotic use (see **Warnings and precautions)**

1. Assist in protecting the gut of children during microbial imbalance from side effects such as diarrhoea and abdominal discomfort
2. Assist with gastrointestinal disorders in infants
3. Assist in restoring alterations of intestinal flora and bacterial flora
4. Assist in the natural balance of bacterial flora, balancing the presence of good and bad bacteria and thus targeting the root of intestinal disorders
5. Support gut health when normal intestinal flora has been disrupted.

2. What you need to know before you take ENTEROGERMINA 2 billion suspension

Do not take ENTEROGERMINA 2 billion suspension:

If you are allergic to any of the ingredients as listed in this Patient Information Leaflet.

Contra-indications:

Hypersensitivity to the active substance or to any of the ingredients.

Warnings and precautions:

During treatment with antibiotics, it is recommended that **ENTEROGERMINA 2 billion suspension** be taken between antibiotic administrations.

Talk to a healthcare professional before taking ENTEROGERMINA 2 billion suspension, if you are immunocompromised (significantly weakened immune system with a reduced ability to fight infections) or are hospitalized due to a serious illness.

Special warnings:

Any presence of visible minute partials in the vials of ENTEROGERMINA 2 billion suspension is due to aggregates (clumping) of *Bacillus clausii* spores; it does not suggest that the product has been altered or is not ready for use.
Shake the vial before use.

This medicinal product is for oral use only:

Do not inject or administer in any other way. Incorrect use of ENTEROGERMINA 2 billion suspension has caused severe anaphylactic reactions such as anaphylactic shock.

ENTEROGERMINA 2 billion suspension should not replace a balanced diet.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your health care provider for advice before taking this medicine.
Pregnancy
There are no relevant data available on the use of ENTEROGERMINA 2 billion suspension in pregnant women.
Breastfeeding
There are no relevant data available on the use of Enterogermina during breastfeeding concerning the composition of the breast milk and the effects on the infant
Fertility
There are no relevant data available on the effect of ENTEROGERMINA 2 billion suspension on human fertility.

Driving and using machines:

Enterogermina has no influence on the ability to drive and use machines.

Side effects:

Not all side effects reported for this medicine are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice

In immunocompromised patients (those with a significantly weakened immune system and a reduced
ability to fight infections) or patients hospitalized due to a serious illness who take ENTEROGERMINA 2 billion suspension, *Bacillus clausii*
may be found in the blood and may lead to a serious blood infection.

Reporting of side effects:

If you or your child get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at CFAO:
  chcsa-za-safety@cfao.com, or
- 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 ENTEROGERMINA 2 billion suspension.

Interactions:

Always tell your health care provider if you are taking any other medicines.

3. How to take ENTEROGERMINA 2 billion suspension

Do not share medicines with any other person.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults: 2-3 vials per day.
Infants and children older 1+ months: 1-2 vials per day.

This medication is for oral use only.
Do not inject or administer in any other way
Shake the vial before use.

Method of administration

Take at regular intervals. Take the vial content as it is or dilute it in water or other beverages (e.g., milk, tea, orange juice)

After opening the vial, consume the preparation within a short time to avoid any pollution of the suspension.

If you take more ENTEROGERMINA 2 billion suspension than you should

Do not take a double dose to make up for a forgotten dose, take your usual dose at the usual time.
No cases of overdose have been reported.
In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

4. How to store ENTEROGERMINA 2 billion suspension

- Store at or below 25 °C.
- Keep in the original container
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container/label.
- Return all unused medicine to your pharmacist for safe disposal.

5. What ENTEROGERMINA 2 billion suspension looks like and contents of the pack.

ENTEROGERMINA 2 billion suspension is a whitish, opalescent, liquid inside low-density polyethylene bottles shaped like a vial. Made by plastics extrusion techniques.
The vials are stored inside a unit carton containing 20 vials.

Registration No:

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Holder of Certificate of Registration:

CFAO Healthcare South Africa (Pty) Ltd.
Atrium on 5th, 6th Floor, Sandton City,
Corner Maude and 5" Street,
Sandton,
Gauteng, 2146

This leaflet was last revised in:

26 November 2024
Date of revision: To be allocated by SAHPRA.

Registration number:

N/A

For full information refer to the package insert and patient information leaflet on web.
www.enterogermina.co.za

Opella.

PASIËNTINLIGTINGSBLAD

enterogermina®

2 miljard / 5 ml orale suspensie
Suikervry

SKEDULERINGSTATUS

S0

KATEGORIE EN KLAS

Klas D: Komplementêre Medisyne:
Gesondheidsaanvulling; 34.9 Probiotika

HANDELSNAAM EN DOSEERVORM

ENTEROGERMINA 2 miljard (orale suspensie)

Elke 5 ml flessie bevat 2 miljard poliantibiotika-weerstandige *Bacillus clausii* spore (stamme SIN, O/C, T, N/R).
Suikervry.

Ander bestanddele:

Gesuiwerde water.

Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir jou.
ENTEROGERMINA 2 miljard suspensie is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid in stand kan hou.
Jy moet **ENTEROGERMINA 2 miljard suspensie** nietemin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie ENTEROGERMINA 2 miljard suspensie met enigiemand anders deel nie.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat is ENTEROGERMINA 2 miljard suspensie en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy ENTEROGERMINA 2 miljard suspensie neem
   a. Kontra-indikasies
   b. Waarskuwings en voorsorgmaatreëls
   c. Moontlike newe-effekte
   d. Interaksies
3. Hoe om ENTEROGERMINA 2 miljard suspensie te neem
4. Hoe om ENTEROGERMINA 2 miljard suspensie te bêre
5. Beskrywing van die inhoud van die pak en inligting oor die houer.

1. Wat is ENTEROGERMINA 2 miljard suspensie en waarvoor word dit gebruik.

ENTEROGERMINA 2 miljard suspensie is 'n gesondheidsaanvulling, probiotika. Wanneer dit op 'n gereelde grondslag ingeneem word, behoort probiotika die mikrobiese balans in die menslike ingewandskanaal te verbeter en te normaliseer, en sodoende die werking van die verteringskanaal verbeter.

Probiotika help om die mikrobiese flora te herstel wat verandered is tydens die gebruik van antibiotika.
Ondersteunende aanvulling gedurende antibiotika gebruik (sien **Waarskuwings en voorsorgmaatreëls**).

1. Help om die ingewandskanaal van kinders teen newe-effekte soos diarree en buikpyn te beskerm wanneer daar 'n mikrobiese wanbalans is.
2. Help met gastro-intestinale versteurings in babas.
3. Help om wysigings in die ingewande se flora en bakteriële flora te herstel.
4. Help in die natuurlike balans van bakteriële flora, balanseer die teenwoordigheid van goeie en slegte bakterieë en teiken sodoende die oorsprong van intestinale versteurings.
5. Ondersteun dermgesondheid wanneer normale intestinale flora ontwrig is.

2. Wat jy moet weet voordat jy ENTEROGERMINA 2 miljard suspensie neem

Moenie ENTEROGERMINA 2 miljard suspensie neem nie:

Indien jy allergies is vir enige van die bestanddele, soos gelys in hierdie Pasiëntinligtingsblad.

Kontra-indikasies:

Hipersensitiwiteit vir die aktiewe stof of vir enige van die bestanddele.

Waarskuwings en voorsorgmaatreëls:

Tydens behandeling met antibiotika word aanbeveel dat **ENTEROGERMINA 2 miljard suspensie** tussen toedienings van die antibiotika geneem word.

Spesiale waarskuwings:

Enige piepklein deeltjies wat in die ENTEROGERMINA 2 miljard suspensie flessies gesien kan word, is weens aggregasie (saambondeling) van *Bacillus clausii* spore; dit dui geensins daarop dat die produk gewysig is of nie gereed vir gebruik is nie.
Skud die flessie voor gebruik.

Indien jy immuungebrekkig is (beduidend verswakte immuunstelsel met verminderde vermoë om infeksies te beveg) of jy weens 'n ernstige siekte gehospitaliseer is, praat met 'n gesondheidsorgdeskundige voordat jy Enterogermina neem.

Hierdie medisinale produk is slegs vir mondelike gebruik.

Moet dit nie inspuit of op enige ander manier toedien nie. Verkeerde gebruik van ENTEROGERMINA 2 miljard suspensie het hewige anafilaktiese reaksies, soos anafilaktiese skok, veroorsaak.

ENTEROGERMINA 2 miljard suspensie moenie in plaas van 'n gebalanseerde dieet gebruik word nie.

Swangerskap, borsvoeding en vrugbaarheid:

Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, vra asseblief jou gesondheidsorgverskaffer se advies voordat jy hierdie medisyne neem.

Swangerskap

Daar is geen relevante data beskikbaar vir die gebruik van ENTEROGERMINA 2 miljard suspensie by swanger vrouens nie.

Borsvoeding

Daar is geen relevante data beskikbaar vir die gebruik van ENTEROGERMINA 2 miljard suspensie tydens borsvoeding rakende die samestelling van borsmelk en die uitwerking op die baba nie.

Vrugbaarheid

Daar is geen relevante data beskikbaar oor die uitwerking van ENTEROGERMINA 2 miljard suspensie op menslike vrugbaarheid nie.

Bestuur en die gebruik van masjiene:

ENTEROGERMINA 2 miljard suspensie het geen invloed op die vermoë om 'n voertuig te bestuur en masjiene te gebruik nie.

Newe-effekte:

Nie alle newe-effekte wat vir hierdie medisyne gerapporteer is, word in hierdie inligtingsblad ingesluit nie.
Indien jou algemene gesondheid agteruitgaan of indien jy enige ongunstige effekte ervaar terwyl jy hierdie medisyne neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

By immuungebrekkige pasiënte (dié met 'n beduidend verswakte immuunstelsel en verminderde vermoë om infeksies te beveg) of pasiënte wat weens 'n ernstige siekte gehospitaliseer is en Enterogermina neem, kan *Bacillus clausii* in die bloed teenwoordig wees en dit kan tot 'n ernstige bloedinfeksie lei.

Rapportering van newe-effekte:

Indien jy of jou kind newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte rapporteer aan: Die Farmakologiese Waaksaamheideenheid by CFAO: chcsa-za-safety@cfao.com, of SAHPRA via die "6.04 Adverse Drug Reaction Reporting Form" (Vorm om ongunstige geneesmiddelreaksies te rapporteer), wat aanlyn by SAHPRA se publikasies beskikbaar is: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van ENTEROGERMINA 2 miljard suspensie te verskaf.

Interaksies:

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem.

3. Hoe om ENTEROGERMINA 2 miljard suspensie te neem

Moenie medisyne met ander mense deel nie.
Neem hierdie medisyne altyd presies soos wat in hierdie inligtingsblad beskryf word, of soos wat jou dokter of apteker vir jou gesê het. Vra gerus jou dokter of apteker indien jy onseker is.

Die aanbevole dosis is:

Volwassenes: 2-3 flessies per dag.
Babas en kinders 1+ maand: 1-2 flessies per dag.

Hierdie medikasie is slegs vir mondelike gebruik. Moet dit nie inspuit of op enige ander manier toedien nie.
Skud die flessie voor gebruik.

Metode van toediening:

Neem met gereelde intervalle. Neem die inhoud van die flessie soos dit is of verdun dit in water of ander drankies (bv. melk, tee, lemoensap).

Nadat die flessie oopgemaak is, drink die bereiding binne 'n kort tydjie om te voorkom dat die suspensie dalk besoedel raak.

Indien jy meer ENTEROGERMINA 2 miljard suspensie neem as wat jy behoort te neem:

Moenie 'n dubbele dosis neem om te vergoed vir 'n dosis wat vergeet is nie, neem jou gebruiklike dosis op die gewone tyd.
Geen gevalle van oordosering is al aangemeld nie.
In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

4. Hoe om ENTEROGERMINA 2 miljard suspensie te bêre

- Bêre by of onder 25 °C.
- Hou in die oorspronklike karton.
- Bêre alle medisyne waar kinders dit nie in die hande kan kry nie.
- Moenie gebruik ná die vervaldatum wat op die houer/etiket gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker vir veilige wegdoening.

5. Hoe ENTEROGERMINA 2 miljard suspensie lyk en inhoud van die pak

ENTEROGERMINA 2 miljard suspensie is 'n witterige, ondeursigtige vloeistof in laedigtheid-poliëtileen-bottels in die vorm van 'n flessie. Vervaardig deur middel van plastiekekstrusieprosesse.
Die flessies word in 'n buitenste karton verpak wat 20 flessies bevat.

Registrasienommer:

Hierdie ongeregistreerde medisyne is nie vir gehalte, veiligheid of beoogde gebruik deur SAHPRA geëvalueer nie.

Houer van die Registrasiesertifikaat

CFAO Healthcare South Africa (Edms.) Bpk.
Atrium on 5th, 6de Vloer, Sandton City
h.v. Maude & 5de Straat
Sandton, Gauteng
2146

Hierdie inligtingsblad is laas hersien

26 November 2024
Datum van hersiening: Sal deur SAHPRA toegeken word.

Registrasienommer

NVT.

Raadpleeg die voubiljet en die inligtingstuk vir pasiënte vir volledige inligting besoek.
www.enterogermina.co.za

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