

PATIENT INFORMATION LEAFLET

Enterogermina®

4 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
ENTERGERMINA 4 billion (oral suspension)
The active substances per 5 ml suspension is:

Each 5 ml vial contains 4 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.
ENTERGERMINA 4 billion suspension is available without a doctor's prescription for you to maintain your health.

Nevertheless, you still need to take ENTERGERMINA 4 billion suspension carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ENTERGERMINA 4 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 ENTERGERMINA 4 billion suspension is and what it is used for.
2. What you need to know before you take ENTERGERMINA 4 billion suspension
 - a. Contra-indications
 - b. Warnings and precautions
 - c. Possible side effects.
 - d. Interactions
3. How to take ENTERGERMINA 4 billion suspension
4. How to store ENTERGERMINA 4 billion suspension
5. Description of contents of the pack and container information.

1. What ENTERGERMINA 4 billion suspension is and what it is used for.

ENTERGERMINA 4 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 in restoring alterations of intestinal flora and bacterial flora
3. Assist in the natural balance of bacterial flora, balancing the presence of good and bad bacteria and thus targeting the root of intestinal disorders
4. Support gut health when normal intestinal flora has been disrupted.

2. What you need to know before you take ENTERGERMINA 4 billion suspension

Do not take ENTERGERMINA 4 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 **ENTERGERMINA 4 billion suspension** be taken between antibiotic administrations.

Talk to a healthcare professional before taking ENTERGERMINA 4 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 particles in the vials of ENTERGERMINA 4 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 ENTERGERMINA 4 billion suspension has caused severe anaphylactic reactions such as anaphylactic shock.

ENTERGERMINA 4 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 ENTERGERMINA 4 billion suspension in pregnant women.

Breastfeeding

There are no relevant data available on the use of ENTERGERMINA 4 billion suspension 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 ENTERGERMINA 4 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 ENTERGERMINA 4 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 : chcsazasafety@cao.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 ENTERGERMINA 4 billion suspension.

Interactions:

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

3. How to take ENTERGERMINA 4 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: 1 vial per day.
- Infants and children older than 1 months: 1 vial 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 ENTERGERMINA 4 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 overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

4. How to store ENTERGERMINA 4 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 ENTERGERMINA 4 billion suspension looks like and contents of the pack.

ENTERGERMINA 4 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 5th Street,
Sandton, Gauteng, 2146.

This leaflet was last revised in:

01 August 2025
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.

PASIENTINLIGTINGSBLAD

Enterogermina®

4 miljard / 5 ml orale suspensie Suikervry

SKEDULERINGSSTATUS [S0]

KATEGORIE EN KLAS
Klas D: Komplementêre Medisyne;
Gesondheidsaanvulling; 34.9 Probiotika

HANDELSNAAM EN DOSEERVORM
ENTEROGERMINA 4 miljard (orale suspensie)
Die aktiewe bestanddele per 5 ml suspensie is:
Eke 5 ml flesse bevat 4 miljard polivalente-veestamige
Bacillus clausii spore (stamme SIN, O/C, T, N/R),
Suikervry.

Ander bestanddele:
Gesuiverde water.

**Lees hierdie hele inligtingsblad aandagdig deur
wat dit bevat inligting wat belangrik is vir jou.**
ENTEROGERMINA 4 miljard suspensie is beskikbaar
sonder 'n dokter se voorskrif, sodat jy jou gesondheid in stand
kan hou.

Jy moet **ENTEROGERMINA 4 miljard suspensie** nielmin
steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit
weer lees.
- Moenie **ENTEROGERMINA 4 miljard suspensie** met
enigiemand anders deel nie.
- Via jou gesondheidsorgverskaffer of apteker indien jy
verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

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

1. Wat is **ENTEROGERMINA 4 miljard suspensie** en waarvoor word dit gebruik.

ENTEROGERMINA 4 miljard suspensie is 'n gesondheidsaan-
vulling, probiotika. Wanneer dit op 'n gereelde grondslag
ingeneem word, behoort probiotika die mikrobiële balans in
die menslike ingewandskanaal te verbeter en te normaliseer,
en sodoende die werking van die vertingskanaal verbeter.

Probiotika help om die mikrobiële flora te herstel wat verand-
ered 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
in mikrobiële wanbalans is.
2. Help om wysigings in die ingewande se flora en bakteriële
flora te herstel.
3. Help in die natuurlike balans van bakteriële flora, balan-
seer die teenwoordigheid van goeie en slegte bakterieë en
helpe sodoende die oorsprong van intestinale versteurings.
4. Ondersteun dermgesondheid wanneer normale intestinale
flora ontwyk is.

2. Wat jy moet weet voordat jy **ENTEROGERMINA** **4 miljard suspensie** neem

Moenie **ENTEROGERMINA 4 miljard suspensie**
neem nie:

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

Kontra-indikasies:
Hipersensiwiteit vir die aktiewe stof of vir enige van die be-
standdele.

Waarskuwings en voorsorgmaatreëls:
Tydens behandeling met antibiotika word aanbeveel dat **EN-
TEROGERMINA 4 miljard suspensie** tussen toedien-
ings van die antibiotika geneem word.

Spesiale waarskuwings:
Enige piepklein deeltjies wat in die **ENTEROGERMINA 4 mil-
jard suspensie** flesgies gesien kan word, is weens aggreegasie
(saambondeling) van *Bacillus clausii* spore; dit is gereeld daar-
op dat die produk gewyng is of nie gereed vir gebruik is nie.
Skud die flesse voor gebruik.

Indien jy immungebreeklik is (beduidend verswakte immuun-
stelsel met verminderde vermoë om infeksies te beveel) of jy
weens 'n ernstige siekte gehospitaliseer is, praat met 'n ge-
sondheidsorgdeskundige voordat jy **Enterogermina** neem.

**Hierdie medisinale produk is slegs vir mondelike
gebruik.**

Moet dit nie inspuul of op enige ander manier toedien nie.
Verkeerde gebruik van **ENTEROGERMINA 4 miljard suspen-
sie** het hevige anafylaktiese reaksies, soos anafylaktiese skok,
veroorzaak.

ENTEROGERMINA 4 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 wies of beplan om swanger te raak, via asse-
blief jou gesondheidsorgverskaffer se advies voordat jy hierdie
medisyne neem.

Swangerskap
Daar is geen relevante data beskikbaar vir die gebruik van

ENTEROGERMINA 4 miljard suspensie by swanger vrouens nie.
Borsvoeding
Daar is geen relevante data beskikbaar vir die gebruik van
ENTEROGERMINA 4 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 4 miljard suspensie** op menslike vrug-
baarheid nie.

Bestuur en die gebruik van masjiene:
ENTEROGERMINA 4 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 immungebreeklike pasiënte (dié met 'n beduidend verswak-
te immuunstelsel en verminderde vermoë om infeksies te beveel)
of pasiënte wat weens 'n ernstige siekte gehospitaliseer is en
Enterogermina neem, kan *Bacillus clausii* in die bloed teenvoor-
dig 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 Waaksaamheidsheid by CFAO:
chcsozasafety@do.com, of SAHPRa via die '0,04 Ad-
verse Drug Reaction Reporting Form' (Vorm om ongunstige
geneesmiddelleaksies te rapporteer), wat aanlyn by SAHPRa
se publikasies beskikbaar is: [https://www.sahpra.org.za/
Publications/Index/8](https://www.sahpra.org.za/Publications/Index/8).

Deur newe-effekte te rapporteer kan jy help om meer inligting
rakende die veiligheid van **ENTEROGERMINA 4 miljard sus-
pensie** te verskaf.

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

3. Hoe om **ENTEROGERMINA 4 miljard suspensie** te neem

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

Die aanbevole dosis is:

Volwassenes: 1 flesse per dag.
Babes en kinders ouer as 1 maand: 1 flesse per dag.
Hierdie medikasie is slegs vir mondelike gebruik. Moet dit nie
inspuul of op enige ander manier toedien nie.
Skud die flesse voor gebruik.

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

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

Indien jy meer **ENTEROGERMINA 4 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 gebruikelike 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 4 miljard suspensie** te bêre

- Bêre by of onder 25 °C.
- Hou in die oorspronklike karton.
- Bêre die 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 4 miljard suspensie** lyk en inhoud van die pak

ENTEROGERMINA 4 miljard suspensie is 'n witterige,
ondrusagtige vloeistof in bedrigtheid-pastieitien-ballets in die
vorm van 'n flesse. Vervoerdig deur middel van plastiek-
stusieprosesse.

Die flesgies word in 'n buiteste karton verpak wat 20 flesgies bevat.

Registrasienuommer:
Hierdie geregistreerde medisyne is nie vir gehalte, veilig-
heid of beoogde gebruik deur SAHPRa geëvalueer nie.

Houer van die Registrasiesertifikaat
CFAO Healthcare South Africa (Edms.) Bpk.
Atrium on 5th, 6de Vloer, Sandton City
t.v.v. Maurice & Sida Street - Sandton, Gauteng 2146

Hierdie inligtingsblad is laas hersien
01 Augustus 2025
Datum van hersiening: Sal deur SAHPRa toegeken word.

Registrasienuommer
NVI

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

Opella.

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