PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC

Zinc citrate trihydrate 6,4 mg
(equivalent to 2 mg elemental zinc)
***Limosilactobacillus reuteri* 1 billion (1 x 10^9) freeze-dried colony forming units (CFU)**
Contains sweetener (220 mg xylitol per 1 ml)

COMPLEMENTARY MEDICINE – HEALTH SUPPLEMENT
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information foryou
ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC are available without a doctor's prescription, for your child to maintain his/her health. Nevertheless, you still need to use ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC carefully to getthe best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC 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 ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC are and what it is used for
2. What you need to know before you give ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC
3. How to give ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC
4. Possible side effects
5. How to store ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC
6. Contents of the pack and other information

1. What ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC are and what it is used for

ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC support the immune system, assists in the treatment and prevention of diarrhoea and constipation and may help ease symptoms of colic.

Zinc is an essential element of nutrition that assists in connective tissue formation, the maintenance of a healthy skin, together with immune function and good health. It also assists the body to metabolise carbohydrates, fats and protein.
Limosilactobacillus reuteri is a species of probiotic bacteria that improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut when used on a regular basis.
Limosilactobacillus reuteri may assist with the relief of colic symptoms.

2. What you need to know before you give ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC

Do not give ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC
- If your child is hypersensitive (allergic) to zinc, *Limosilactobacillus reuteri* or any of the other ingredients of ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC (listed in section 6).

Warnings and precautions
Zinc and *Limosilactobacillus reuteri* are considered safe if taken at the recommended dosage.
Health supplements should not replace a balanced diet.
Giving multiple supplements and multivitamins may cause a cumulative intake of certain vitamins, minerals and other substances.
Do not exceed the indicated dose except on medical advice from a health care provider.
Consult your health care provider first if you are also giving your child other medicines.

Other medicines and ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC
Always tell your health care provider if you are giving your child any other medicine. (This includes all complementary or traditional medicines.)
- Taking ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC with antibiotics mightdecreasethe effectiveness of ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC. Take ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC two to three hours before or after antibiotics.
- The absorption of zinc may be reduced by taking calcium, iron or magnesium containing supplements, or phosphorus-containing preparations at the sametime.
- Zinc can reduce the absorption of copperwhen taken at the sametime.
- By taking zinc supplements with penicillamine or antibiotics such as tetracyclines or quinolones, the effectiveness of these medicines can be reduced.
- Taking zinc with ritonaviror cephalexin might reduce serum levels preventing absorption.

ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC with food and drink
Taking ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC with milk containing products might reduce the absorption of zinc.

Pregnancy, breastfeeding and fertility
ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC is indicated for use in children.
If you are pregnant or breastfeeding, thinkyou may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC.
Zinc is distributed into breast milk and therefore supplied to breastfed infants.

Driving and using machines
ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC is indicated for use in children.
ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC will most likely not affect the ability to drive or operate heavy machines.

3. How to give ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC

Do not share medicines prescribed for you with anyother person.
Always give ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctoror pharmacist if you are not sure.

The usual dose for children is:
0 - 3 years: Give 1 ml daily, especially during and after antibiotic treatment.
Give 2 - 3 hours before or after antibiotics.

ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC should be given at the same time every day for best results.
Do not exceed the recommended dose.
Give 2 hours before or after the use of other medicines.

If you give more ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forgetto give ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC
Do not give a double dose to make up for forgotten individual doses.

4. Possible side effects

ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC can have side effects.
Not all side effects reported for ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC are included in this leaflet. Should your childs general health worsen or if he/she experience any untoward effects while taking ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC, please consult your health care provider for advice.

If any of the following happens, stop giving your child ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting

These are all very serious side effects. If your child has them, he/she may have had a serious reaction to ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC. He/She may need urgent medical attention or hospitalisation.

Tell your doctor if your child notices any of the following:
- abdominal cramps, diarrhoea, metallic taste, nausea and vomiting;

If your child notices 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 or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions 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 ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC.

5. How to store ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC

Store all medicines out of reach of children.
- Store at or below 25 °C, in a cool dry place.
- Keep the bottle tightly closed.
- Protectfrom light and moisture.
- Do not use after the expiry date stated on the carton and bottle.
- 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 ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC contain
- The active substances per 1 ml are:
  Zinc citratetrihydrate 6,4 mg (equivalent to 2 mg elemental zinc)
  Limosilactobacillus reuteri 1 billion (1 x 10^9) freeze-dried colony forming units (CFU)
- The other ingredients are:
  Citric acid monohydrate, sodium carboxymethylcellulose, sodium bicarbonate, purified water
- Contains preservative: potassium sorbate 0,15 % m/v
- Contains sweetener: 220 mg xylitol per 1 ml

What ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC look like and contents of the pack
ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC is a cream-coloured liquid.
ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC is packed in an amber glass bottle with a measured dropper. The bottle is packed in an outer carton.
Pack size: 30 ml

Holder of Certificate of Registration
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Registration number
To be allocated by the SAHPRA

Access to the corresponding Professional Information
www.zinplex.co.za

ZA-ZIMDR01-OPL011

PASIËNTINLIGTINGSTUK

SCHEDULING STATUS: S0

ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC

Sink sitraattrihidraat 6,4 mg
(gelykstaande aan 2 mg elementele sink)
***Limosilactobacillus reuteri* 1 miljard (1 x 10^9) gevriesdroogde kolonievormende eenhede (KVE)**
Bevat versoeter (220 mg xylitol per 1 ml)

KOMPLEMENTÊRE MEDISYNE - GESONDHEIDSAANVULLING
Hierdie ongeregistreerde medisyne is nie geëvalueer deur die SAHPRA vir die kwaliteit, veiligheid of aangeduide gebruik nie.

Lees hierdie hele inligtingstuk sorgvuldig aangesien dit belangrike inligting vir jou bevat
ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC is beskikbaar vir jou sonder 'n dokters voorskrif om jou kind se gesondheid instand te hou. Jy moet egter steeds ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC versigtig gebruik om die beste resultate daarvan te kry.
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Moetnie ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC met enige persoon deel nie.
- Vra jou mediese praktisyn of apteker indien jy meer inligting of advies benodig.

Wat is in hierdie inligtingstuk
1. Wat is ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC en waarvoorword dit gebruik
2. Wat jy moetweet voordat jy ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC gee
3. Hoe om ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINCte gee
4. Moontlike newe-effekte
5. Hoe om ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC te stoor
6. Inhoudvan die pakkie en ander inligting

1. Wat is ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC en waarvoor word dit gebruik

ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC ondersteun die immuunstelsel, help met die behandeling en voorkoming van diarree en hardlywigheid en kan help om simptome van koliek te verlig.

Sink is 'n noodsaaklike element van voeding wat help met vorming van bindweefsel, die instandhouding van 'n gesonde vel tesame met immuunfunksie en goeie gesondheid. Dit help ookdie liggaam om koolhidrate, vette en proteïene te metaboliseer.
Limosilactobacillus reuteri is 'n spesie probiotiese bakterieë wat die mikrobiese balans in die menslike ingewande verbeter of normaliseer en sodoende die funksionering van die spysverteringskanaal/derm verbeter wanneer dit op 'n gereelde basisgebruikword.
Limosilactobacillus reuteri kan bydra tot die verligting van koliek simptome.

2. Wat jy moet weet voordat jy ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC gee

Moenie ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC gee
- As jou kind hipersensitief (allergies) is vir sink, *Limosilactobacillus reuteri* of vir enige van die ander bestanddele van ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC (gelys in deel 6).

Waarskuwings en voorsorgmaatreëls
Sink en *Limosilactobacillus reuteri* word as veilig beskou as dit teen die aanbevole dosis geneem word.
Gesondheidsaanvullings behoortnie 'n gebalanseerde dieette vervang nie.
Die neem van veelvuldige aanvullings en multivitamiene kan 'n kumulatiewe inname van sekere vitamiene, minerale en ander stowwe veroorsaak.
Moenie die aanbevole dosis oorskry nie, behalwe op mediese advies van 'n gesondheidsorgverskaffer.
Raadpleeg eers jou gesondheidsorgverskaffer as jy jou kind ook ander medisyne gee.

Ander medisyne en ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC
Stel altyd jou gesondheidsorgverskaffer in kennis as jy jou kind enige ander medisyne gee. (Ditsluitalle aanvullende of tradisionele medisyne in.)
- Die neem van ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINCsaam met antibiotikakan die doeltreffendheid van ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINCverminder. Neem ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC twee tot drie urevoorof na antibiotika.
- Die absorpsie van sink kan verminderword deur kalsium-, yster- of magnesiumbevattende aanvullings, of fosforbevattende middels gelyktydig te neem.
- Sinkkan die absorpsievan koperverminderwanneerdit gelyktydig geneem word.
- Deur sinkaanvullings saam met penisillamien of antibiotika soos tetrasikliene of kinolonete neem, kan die doeltreffendheid van hierdie medisynes verminderword.
- Die neem van sink saam met ritonavir of kefaleksien kan serumvlakke verlaag en sodoende absorpsie verhoed.

ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC saam met kos en drinkgoed
Die neem van ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC saam met melkbevattende produkte kan die absorpsie van sink verminder.

Swangerskap, borsvoeding en vrugbaarheid
ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC is aangedui vir gebruik by kinders.
As jy swanger is of borsvoed, vermoed dat jy dalk swanger is of swangerskap beplan, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC neem.
Sink word in borsmelk oorgedra en word dus aan borsgevoede babas verskaf.

Bestuur en gebruik van masjinerie
ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC is aangedui vir gebruik by kinders.
ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC sal heel waarskynlik nie jou bestuursvermoë of die vermoë om masjinerie te gebruik of daarmee te werk affekteernie.

3. Hoe om ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC te gee

Moet nie medisyne watvir jou voorgeskryf is met enige ander persoon deel nie.
Gee ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC altyd presies soos aangedui in hierdie voubiljet of soos deur jou dokter of apteker aangedui. Raadpleeg jou dokter of apteker as jy nie seker is nie.

Die normale dosis vir kinders is:
0 – 3 jaar: Gee 1 ml daagliks, veral tydens en na antibiotiese behandeling.
Gee 2 - 3 uurvoor of na antibiotika.

ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC moet elke dag op dieselfde tyd gegee word vir die beste resultate.
Moet nie die aanbevole dosis oorskry nie.
Neem twee ure voor of na die gebruik van ander medisyne.

As jy meer ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC gegee het as watjy moet
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien een nie beskikbaar is nie, kontak die naaste hospitaal of vergiftigings beheersentrum.

As jy vergeet het om ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC te gee
Moenie 'n dubbele dosis gee om op te maak vir die vergete dosis nie.

4. Moontlike newe-effekte

ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC kan newe-effekte hê.
Nie alle newe-effekte wat vir ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC aangemeld is, is in hierdie voubiljet ingesluit nie. Indien jou kind se algemene gesondheid verswak of indien hy/sy enige ongewenste effekte ervaar terwyl hy/sy ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC te gee en kontak jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- uitslag of jeuk,
- floutes

Hierdie is alles baie ernstige newe-effekte.As jou kind dit het, het hy/sy dalk 'n ernstige reaksie op ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC gehad. Hy/Sy mag dalk dringende mediese aandag of hospitalisasie benodig.

Stel jou dokter in kennis as jou kind enige van die volgende opmerk:
- abdominale krampe, diarree, metaalsmaak, naarheid en braking;

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

Rapportering van newe-effekte
Indien jy newe-effekte ervaar, gesels met jou dokter of apteker. Jy kan ook die newe-effekte rapporteer aan SAHPRA deur die "6.04 Adverse Reaction Reporting Form" wat aanlyn beskikbaar is onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte te rapporteer kan jy help om meer inligting te verskaf oor die veiligheid van ZINPLEX® JUNIOR PROBIOTIC DROPSWITH ZINC.

5. Hoe om ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC te stoor

Stoor alle medisyne buite bereikvan kinders.
- Bewaar by of benede 25 °C, in 'n koel droë plek.
- Die bottel moet dig toe wees.
- Beskermteen lig envog.
- Moet nie na die vervaldatum wat op die karton en bottel aangedui is gebruik nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie ongebruikte medisyne in afvoerpype of rioolsisteme (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting

Wat is in ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC
- Die aktiewe bestanddele in elke 1 ml is:
  Sink sitraattrihidraat 6,4 mg (gelykstaande aan 2 mg elementele sink)
  Limosilactobacillus reuteri 1 miljard (1 x 10^9) gevriesdroogde kolonievormende eenhede (KVE)
- Die ander bestanddele is:
  Sitroensuurmonohidraat, natriumkarboksimetielsellulose, natriumbikarbonaat, gesuiwerde water
- Bevat preserveermiddel: kaliumsorbaat 0,15 % m/v
- Bevatversoeter: 220 mg xylitol per 1 ml

Hoe ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC lyk en die inhoud van diehouer
ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC is 'n roomkleurigevloeistof.
ZINPLEX® JUNIOR PROBIOTIC DROPS WITH ZINC word in 'n amberkleurige glasbottel met 'n afgemete drupper verpak. Die bottel is verpak in 'n kartonhouer.
Verpakkingsgrootte: 30 ml

Houervan die Registrasiesertifikaat
HOUSE OF ZINPLEX (Edms) Bpk
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Republiek van Suid-Afrika
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Hierdie inligtingstuk is laas hersien in
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Registrasie Nommer
Om deurdie SAHPRA toegeken teword.

Toegang tot die ooreenstemmende Professionele Inligting
www.zinplex.co.za

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