PATIENT INFORMATION LEAFLET FOR BRUNEL BASICS IMMUNE BOOSTER JUNIOR

SCHEDULING STATUS
S0

BRUNEL BASICS IMMUNE BOOSTER JUNIOR syrup
Pelargonium sidoides DC (african geranium), L-ascorbic acid (vitamin C), zinc gluconate, thiamine hydrochloride, riboflavin 5 phosphate, pyridoxine hydrochloride, folic acid.
Preservatives: Potassium sorbate 0,15 % *m/v*, sodium benzoate 0,3 % *m/v*.
Contains sugar: Each 5 ml contains 218 mg fructose.
Contains sweetener: Each 5 ml contains 3,72 mg sucralose.

COMPLEMENTARY MEDICINE: D33.7 COMBINATION PRODUCT
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 for you.
BRUNEL BASICS IMMUNE BOOSTER JUNIOR is available without a doctor's prescription, for you to maintain your child's health. Nevertheless, you still need to give your child BRUNEL BASICS IMMUNE BOOSTER JUNIOR carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What BRUNEL BASICS IMMUNE BOOSTER JUNIOR is, and what it is used for.
2. What you need to know before you give your child BRUNEL BASICS IMMUNE BOOSTER JUNIOR.
3. How to give your child BRUNEL BASICS IMMUNE BOOSTER JUNIOR.
4. Possible side effects.
5. How to store BRUNEL BASICS IMMUNE BOOSTER JUNIOR.
6. Contents of the pack and other information.

1. What BRUNEL BASICS IMMUNE BOOSTER JUNIOR is, and what it is used for

BRUNEL BASICS IMMUNE BOOSTER JUNIOR helps to maintain normal immune function in children.

2. What you need to know before you give your child BRUNEL BASICS IMMUNE BOOSTER JUNIOR

Do not give your child BRUNEL BASICS IMMUNE BOOSTER JUNIOR:

- if your child is under the age of 2 years;
- if your child is hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of BRUNEL BASICS IMMUNE BOOSTER JUNIOR (see **What BRUNEL BASICS IMMUNE BOOSTER JUNIOR contains**);
- if your child suffers from hyperoxaluria (when there is too much oxalate in the urine. Oxalate is a natural chemical the body makes), as BRUNEL BASICS IMMUNE BOOSTER JUNIOR contains vitamin C;
- if your child has kidney disease or renal failure;
- if your child has liver disease/problems.

Warnings and precautions

BRUNEL BASICS IMMUNE BOOSTER JUNIOR contains preservatives:
BRUNEL BASICS IMMUNE BOOSTER JUNIOR contains potassium sorbate and sodium benzoate, which may cause allergic reactions.

BRUNEL BASICS IMMUNE BOOSTER JUNIOR contains sucralose & fructose:
BRUNEL BASICS IMMUNE BOOSTER JUNIOR contains sucralose and fructose. The content of sucralose (and fructose) in medicines for oral use may affect how other medicines are absorbed when taken at the same time.

Other medicines and BRUNEL BASICS IMMUNE BOOSTER JUNIOR
Always tell your healthcare provider if your child is taking any other medicine. (This includes all complementary or traditional medicines.)

- If your child is currently taking antibiotics (quinolones or tetracyclines) you must not give them to your child together with BRUNEL BASICS IMMUNE BOOSTER JUNIOR. The antibiotic should be given at least 2 hours before, or 4 – 6 hours after the BRUNEL BASICS IMMUNE BOOSTER JUNIOR.

BRUNEL BASICS IMMUNE BOOSTER JUNIOR with food and drink
See section 3 (**How to use BRUNEL BASICS IMMUNE BOOSTER JUNIOR)**.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking BRUNEL BASICS IMMUNE BOOSTER JUNIOR.
Safety and efficacy of BRUNEL BASICS IMMUNE BOOSTER JUNIOR during pregnancy and breastfeeding have not been established.
BRUNEL BASICS IMMUNE BOOSTER JUNIOR is indicated for use in children only.

Driving and using machines
BRUNEL BASICS IMMUNE BOOSTER JUNIOR is not likely to affect your child's ability in performing tasks requiring their attention.

3. How to give your child BRUNEL BASICS IMMUNE BOOSTER JUNIOR
Do not share your child's medicines with any other person.
Always give your child BRUNEL BASICS IMMUNE BOOSTER JUNIOR 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 usual dose is:
Children 2 – 3 years: 2,5 ml (half a medicine measure) three times per day.
Children 4 – 8 years: 5 ml (one medicine measure) three times per day.
Children 8 years and older: 10 ml (two medicine measures) three times per day.

If you have the impression that the effect of BRUNEL BASICS IMMUNE BOOSTER JUNIOR is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.
Shake the bottle well before use.
BRUNEL BASICS IMMUNE BOOSTER JUNIOR can be taken with or without food.

If you give your child more BRUNEL BASICS IMMUNE BOOSTER JUNIOR than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Take this leaflet and the rest of the remaining BRUNEL BASICS IMMUNE BOOSTER JUNIOR with you so the doctor will know what you or your child have taken.

4. Possible side effects
BRUNEL BASICS IMMUNE BOOSTER JUNIOR can have side effects.
Not all side effects reported for BRUNEL BASICS IMMUNE BOOSTER JUNIOR are included in this leaflet.
Should your child's general health worsen or if your child experiences any untoward effects while taking BRUNEL BASICS IMMUNE BOOSTER JUNIOR, please consult your healthcare provider for advice.

If any of the following happens, stop giving your child BRUNEL BASICS IMMUNE BOOSTER JUNIOR and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of your child's hands, feet, ankles, face, lips, 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, your child may have had a serious allergic reaction to BRUNEL BASICS IMMUNE BOOSTER JUNIOR and may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following in your child:

- chest pain;
- angina;
- changes in the way your child's heart beats, for example, if you notice it beating faster;
- difficulty breathing.

These are all serious side effects. Your child may need urgent medical attention.

Tell your doctor if your child experiences any of the following:

Side effects occurring with an unknown to rare frequency:

- nausea (feeling sick);
- vomiting (being sick);
- diarrhoea (runny, loose stool);
- abdominal pain (stomach cramps);
- esophagitis (inflammation of the oesophagus- the muscular tube that delivers food from your mouth to your stomach);
- heartburn;
- gastrointestinal obstruction (blockage in the intestines/gut);
- dysphagia (difficulty in swallowing);
- loss of appetite;
- metallic taste;
- dry mouth;
- mouth irritation;
- mild nasal and gingival bleeding (bleeding of the nose and gums);
- headache;
- drowsiness;
- fatigue;
- insomnia (having trouble falling or staying asleep);
- flushing (skin becomes red and/or hot);
- paraesthesia ("pins and needles");
- dermatitis (common skin irritation);
- hypersensitivity reactions;
- polyuria (when the body produces too much urine);
- chromaturia (any abnormal colouration of the urine);
- decreased serum folic acid concentrations.

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

Reporting of side effects

If your child gets 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 BRUNEL BASICS IMMUNE BOOSTER JUNIOR.

5. How to store BRUNEL BASICS IMMUNE BOOSTER JUNIOR

- Store all medicines out of reach of children.
- Store at or below 25 °C in a cool, dry place, protected from light.
- Do not store in a bathroom.
- Do not use after the expiry date printed on the label.
- Keep the bottle tightly closed.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BRUNEL BASICS IMMUNE BOOSTER JUNIOR contains

Each 5 ml contains:

The active substances are:

Pelargonium sidoides DC (African geranium)	125 mg
[root, 1:10 extract providing 12,5 mg dried herb equivalent]	
L-Ascorbic acid (Vitamin C)	120 mg
Zinc gluconate	35 mg
providing Zinc (elemental)	5 mg
Thiamine hydrochloride	1,2 mg
providing Thiamine (Vitamin B_1)	0,94 mg
Riboflavin 5 phosphate	1,3 mg
providing Riboflavin (Vitamin B_2)	0,95 mg
Pyridoxine hydrochloride	1,7 mg
providing Pyridoxine (Vitamin B_6)	1,4 mg
Folic acid	150 µg

The other ingredients are citric acid monohydrate (E330), cream soda flavour 3857/W, fructose crystals, glycerine BP (E422), lime green colourant, potable water, potassium sorbate (E202), sodium benzoate (E211), sodium bicarbonate (E500), sodium carboxymethyl cellulose (E466), and sucralose (E955).

What BRUNEL BASICS IMMUNE BOOSTER JUNIOR looks like and contents of the pack

200 ml fluorescent lime green solution, with a cream soda flavour and distinct vitamin taste, packed in a black PET bottle.

Holder of Certificate of Registration

Brunel Laboratoria (Pty) Ltd
1 Van Tonder Street
Sunderland Ridge
Centurion
0157
info@brunel.co.za

This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

Access to the corresponding Professional Information

The Professional Information for BRUNEL BASICS IMMUNE BOOSTER JUNIOR is available on https://www.brunel.co.za/professional-information/ or can be requested from the contact details above.

PASIËNTINLIGTINGSBLAD VIR BRUNEL BASICS IMMUNE BOOSTER JUNIOR

SKEDULERINGSTATUS
S0

BRUNEL BASICS IMMUNE BOOSTER JUNIOR stroop
Pelargonium sidoides DC (afrika geranium), L-askorbiensuur (vitamien C), sinkglukonaat, tiamienhidrochloried, riboflavien 5 fosfaat, piridoksien hidrochloried, foliensuur.
Preserveermiddels: Kaliumsorbaat 0,15 % *m/v*, natriumbensoaat 0,3 % *m/v*.
Bevat suiker: Elke 5 ml bevat 218 mg fruktose.
Bevat versoeter: Elke 5 ml bevat 3,72 mg sukralose.

KOMPLEMENTÊRE MEDISYNE: D33.7 KOMBINASIEPRODUK
Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

Lees hierdie hele inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou.
BRUNEL BASICS IMMUNE BOOSTER JUNIOR is beskikbaar sonder ’n dokter se voorskrif, vir jou om jou kind se gesondheid te onderhou. Nietemin, moet jy BRUNEL BASICS IMMUNE BOOSTER JUNIOR versigtig vir jou kind gee om die beste resultate daaruit te kry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat BRUNEL BASICS IMMUNE BOOSTER JUNIOR is, en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy BRUNEL BASICS IMMUNE BOOSTER JUNIOR vir jou kind gee.
3. Hoe om BRUNEL BASICS IMMUNE BOOSTER JUNIOR vir jou kind te gee.
4. Moontlike newe-effekte.
5. Hoe om BRUNEL BASICS IMMUNE BOOSTER JUNIOR te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat BRUNEL BASICS IMMUNE BOOSTER JUNIOR is, en waarvoor dit gebruik word
BRUNEL BASICS IMMUNE BOOSTER JUNIOR help om normale immuunfunksie by kinders te handhaaf.

2. Wat jy moet weet voordat jy BRUNEL BASICS IMMUNE BOOSTER JUNIOR vir jou kind gee
Moet nie BRUNEL BASICS IMMUNE BOOSTER JUNIOR vir jou kind gee:

- indien jou kind onder die ouderdom van 2 jaar is nie;
- indien jou kind hipersensitief (allergies) is vir enige van die aktiewe bestanddele of vir enige van die ander bestanddele van BRUNEL BASICS IMMUNE BOOSTER JUNIOR nie (sien **BRUNEL BASICS IMMUNE BOOSTER JUNIOR bevat**);
- Indien jou kind ly aan hiperoksalurie (wanneer daar te veel oksalaat in die urine is. Oksalaat is 'n natuurlike chemikalie wat die liggaam maak), want BRUNEL BASICS IMMUNE BOOSTER JUNIOR bevat vitamien C;
- indien jou kind niersiekte of nierversaking het nie;
- indien jou kind lewersiekte/probleme het nie.

Waarskuwings en voorsorgmaatreëls

BRUNEL BASICS IMMUNE BOOSTER JUNIOR bevat preserveermiddels:
BRUNEL BASICS IMMUNE BOOSTER JUNIOR bevat kaliumsorbaat en natriumbensoaat, wat allergiese reaksies kan veroorsaak.

BRUNEL BASICS IMMUNE BOOSTER JUNIOR bevat sukralose en fruktose:
BRUNEL BASICS IMMUNE BOOSTER JUNIOR bevat sukralose en fruktose. Die inhoud van sukralose (en fruktose) in medisyne vir orale gebruik kan beïnvloed hoe ander medisyne geabsorbeer word wanneer dit gelyktydig geneem word.

Ander medisyne en BRUNEL BASICS IMMUNE BOOSTER JUNIOR
Sê altyd vir jou gesondheidsorgverskaffer indien jou kind enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- Indien jou kind tans antibiotika (kinolone of tetrasikliene) neem moet jy dit nie saam met BRUNEL BASICS IMMUNE BOOSTER JUNIOR vir jou kind gee nie. Die antibiotika moet ten minste 2 ure voor, of 4 – 6 ure na die BRUNEL BASICS IMMUNE BOOSTER JUNIOR gegee word.

BRUNEL BASICS IMMUNE BOOSTER JUNIOR met eet- en drinkgoed
Sien afdeling 3 (**Hoe om BRUNEL BASICS IMMUNE BOOSTER JUNIOR vir jou kind te gee**).

Swangerskap, borsvoeding en vrugbaarheid
Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy BRUNEL BASICS IMMUNE BOOSTER JUNIOR neem.
Die veiligheid en effektiwiteit van BRUNEL BASICS IMMUNE BOOSTER JUNIOR tydens swangerskap en borsvoeding is nie vasgestel nie.
BRUNEL BASICS IMMUNE BOOSTER JUNIOR word slegs vir gebruik by kinders aangedui.

Bestuur en die gebruik van masjiene
Dit is onwaarskynlik dat BRUNEL BASICS IMMUNE BOOSTER JUNIOR jou kind se vermoë om take uit te voer wat konsentrasie verg, sal affekteer.

3. Hoe om BRUNEL BASICS IMMUNE BOOSTER JUNIOR vir jou kind te gee
Moet nie jou kind se medisyne met enige ander persoon deel nie.
Gee BRUNEL BASICS IMMUNE BOOSTER JUNIOR 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 gewone dosis is:
Kinders 2 – 3 jarige ouderdom: 2,5 ml (halwe medisyne maat) drie keer per dag.
Kinders 4 – 8 jarige ouderdom: 5 ml (een medisyne maat) drie keer per dag.
Kinders 8 jaar en ouer: 10 ml (twee medisyne mate) drie keer per dag.

Indien jy die indruk kry dat die uitwerking van BRUNEL BASICS IMMUNE BOOSTER JUNIOR te sterk of te swak is, bespreek dit met jou dokter of apteker.

Moet nie die aanbevole dosis oorskry nie.
Skud die bottel goed voor gebruik.
BRUNEL BASICS IMMUNE BOOSTER JUNIOR kan met of sonder kos geneem word.

As jy meer BRUNEL BASICS IMMUNE BOOSTER JUNIOR vir jou kind gegee het as wat jy moet
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.
Neem hierdie inligtingsblad en die oorblywende BRUNEL BASICS IMMUNE BOOSTER JUNIOR saam met jou sodat die dokter kan sien wat jy of jou kind ingeneem het.

4. Moontlike newe-effekte
BRUNEL BASICS IMMUNE BOOSTER JUNIOR kan newe-effekte hê.
Nie alle newe-effekte wat vir BRUNEL BASICS IMMUNE BOOSTER JUNIOR gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou kind se algemene gesondheid verswak of jou kind enige ongunstige effekte ondervind terwyl BRUNEL BASICS IMMUNE BOOSTER JUNIOR geneem word, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om BRUNEL BASICS IMMUNE BOOSTER JUNIOR vir jou kind te gee en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van jou kind se hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk of asemhaling;

- uitslag of gejeuk;
- floute.

Hierdie is baie ernstige newe-effekte. Indien jou kind enige daarvan ondervind, mag jou kind ’n ernstige allergiese reaksie op BRUNEL BASICS IMMUNE BOOSTER JUNIOR gehad het. Dringende mediese bystand of hospitalisasie mag nodig wees.

Vertel jou dokter onmiddellik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy een van die volgende by jou kind opmerk:

- borspyn;
- angina;
- veranderinge in die manier waarop jou kind se hart klop, byvoorbeeld as jy opmerk dat dit vinniger klop;
- asemhalingsprobleme.

Hierdie is ernstige newe-effekte. Jou kind kan dringend mediese hulp benodig.

Sê vir jou dokter indien jy enige van die volgende by jou kind opmerk:
Newe-effekte wat voorkom met 'n onbekende tot seldsame frekwensie:

- naarheid;
- braking;
- diarree;
- abdominale pyn (maagkrampe);
- esofagitis (ontsteking van die slukderm - die spierbuis wat kos van jou mond na jou maag vervoer);
- sooibrand;
- gastro-intestinale obstruksie (blokkasie in die ingewande/derm);
- disfagie (moeilik om te sluk);
- verminderde eetlus;
- metaalsmaak;
- droë mond;
- mond irritasie;
- geringe bloeding van die neus en tandvleis;
- hoofpyn;
- lomerigheid;
- moegheid;
- slapeloosheid (sukkel om aan die slaap te raak of aan die slaap te bly);
- blosing (vel word rooi en/of warm);
- parestesie (“spelde en naalde”);
- dermatitis (algemene velirritasie);
- hipersensitiwiteitsreaksies;
- poliurie (wanneer die liggaam te veel urine produseer);
- chromaturie (enige abnormale kleur van die urine);
- verlaagde serumfoliensuurkonsentrasies.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van newe-effekte
Indien jou kind enige newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die “**6.04 Adverse Drug Reactions Reporting Form**”, wat aanlyn **by SAHPRA se publikasies** beskikbaar is: http://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van BRUNEL BASICS IMMUNE BOOSTER JUNIOR te verskaf.

5. Hoe om BRUNEL BASICS IMMUNE BOOSTER JUNIOR te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 °C in ‘n koel, droë plek, en beskerm teen lig.
- Moet nie in die badkamer bêre nie.

- Moet nie gebruik word na die vervaldatum wat op die etiket gedruk is nie.
- Hou die bottel dig toe.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat BRUNEL BASICS IMMUNE BOOSTER JUNIOR bevat

Elke 5 ml bevat:

Die aktiewe bestanddele is:

Pelargonium sidoides DC (Afrika geranium)	125 mg
[wortel, 1:10 ekstrak lewer 12,5 mg gedroogde kruie ekwivalent]	
L-Askorbiensuur (Vitamien C)	120 mg
Sinkglukonaat	35 mg
lewer Sink (elementaal)	5 mg
Tiamienhidrochloried	1,2 mg
lewer Tiamien (Vitamien B_1)	0,94 mg
Riboflavien 5 fosfaat	1,3 mg
lewer Riboflavien (Vitamien B_2)	0,95 mg
Piridoksien hidrochloried	1,7 mg
lewer Piridoksien (Vitamien B_6)	1,4 mg
Foliensuur	150 µg

Die ander bestanddele is *cream soda*-geur 3857/W, fruktosekristalle, gliserien BP (E422), kaliumsorbaat (E202), lemmetjiegroen kleurstof, natriumbensoaat (E211), natriumbikarbonaat (E500), natriumkarboksimetielsellulose (E466) sitroensuurmonohidraat (E330) sukralose (E955) en water.

Hoe BRUNEL BASICS IMMUNE BOOSTER JUNIOR lyk en die inhoud van die verpakking

200 ml fluoresserende lemmetjiegroen oplossing, met 'n *cream soda*-geur en kenmerkende vitamiensmaak, verpak in 'n swart PET-bottel.

Houer van die Registrasiesertifikaat

Brunel Laboratoria (Edms) Bpk
Van Tonderstraat 1
Sunderland Ridge
Centurion
0157
info@brunel.co.za

Hierdie inligtingsblad is hersien in

Sal met registrasie deur SAHPRA aangedui word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad

Die Professionele Inligtingsblad vir BRUNEL BASICS IMMUNE BOOSTER JUNIOR is beskikbaar by https://www.brunel.co.za/professional-information/ of dit kan aangevra word deur die kontakbesonderhede hier bo te gebruik.