

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

[S0]

EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR 100 ml, 200 ml

CONTAINS:

Hedera Helix (Ivy) [leaf], *Matricaria chamomilla* (Chamomile) [flower].

- Complementary Medicine: Discipline specific D33.6 – Western Herbal Medicine.
- A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance. 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

- EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR is available without a doctor's prescription. Nevertheless, you still need to use EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR is and what it is used for
2. What you need to know before you take EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR
3. How to take EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR
4. Possible side effects
5. How to store EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR
6. Contents of the pack and other information

1. What EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR is and what it is used for

EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR offers day-and-night relief* for coughs with a formula, powered by Ivy Leaf extract, to assist with opening airways, relieving coughs, and inflammation. Including soothing chamomile.

*Efficacy of support may vary between users.

2. What you need to know before you take EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR

Do not take EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR:

- If you are hypersensitive (allergic) to any of the ingredients of EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR (listed in section 6 **Contents of pack and other information**).
- If you are pregnant or breastfeeding as EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR (see **Pregnancy, breastfeeding and fertility**).
- Individuals with a history of bleeding disorders or taking anticoagulants (e.g., warfarin) may need to avoid use due to the risk of bleeding.
- May interact with sedatives, alcohol, or CNS depressants, enhancing drowsiness. (see **Other medicines and EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR**).
- If you are taking any chronic medication do not use this product without consulting your medical practitioner.

Warnings and precautions

- Special care should be taken with EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR. Consult a healthcare provider before use if you have:
 - bleeding disorders;
 - known allergy to plants in the Asteraceae family (e.g., ragweed, daisies, marigolds).
 - Do not exceed the daily recommended dose.
 - Do not use after the date of expiry.
- Products containing herbal ingredients may interact with some medication.

Porphyria: Safety has not been established.

Tell your doctor if you are not sure about any of the above.

Other medicines and EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR

Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicines.

Consult your doctor, pharmacist or healthcare provider before use if you are taking:

- blood thinners (anticoagulant - or antiplatelet medication) e.g. warfarin, as some of the ingredients may have a blood thinning effect increasing the risk of bleeding;

Taking EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR with food, drink and alcohol

There is no known interaction between contents of EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR and food, drink and alcohol.

Pregnancy, breastfeeding and fertility

Do not use EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR if you are pregnant or breastfeeding as safety has not been established. 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 this medicine.

Driving and using machines

EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR should not affect your ability to drive or use machinery. However, if you think you are affected you should not drive or operate machinery until you feel better.

It is not always possible to predict to what extent EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR may interfere with your daily activities. Ensure that you do not engage in the above activities until you are aware of the measure to which EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR affects you.

3. How to take EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR

Do not share medicines with any other person.

Always take EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are unsure.

Infants under 1 years old, weighing 3,4 kg (7,5 lbs):

Take 1,5 ml, twice a day.

Consult a healthcare professional if use exceeds 7 days.

Children 1 to 5 years, weighing 12 kg (26,5 lbs) or more:

Take 2,5 ml, three times daily for at least a week.

Consult a healthcare professional if use exceeds 10 days.

Children 6 to 11 years:

Take 5 ml three times daily for at least a week.

Consult a healthcare professional if use exceeds 10 days.

(see **Other medicines and EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR**).

If you take more EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither are available, contact the nearest hospital or poison centre.

If you forget to take EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR

Take your missed dose when you remember. Do not take a double dose to make up for forgotten individual doses.

If you stop taking EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR

If you are taking the dose as indicated, it is unlikely that there should be withdrawal effects when you stop using this medication.

4. Possible side effects

EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR can have side effects. Not all side effects reported for EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR, please consult your healthcare provider for advice.

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: skin rashes, hives (skin bumps), itchiness, swelling of the face, lips mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR. You 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:

Frequency unknown:

- Hypersensitivity reactions or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria (hives), skin rash and itching.
- Abdominal discomfort, - pain, - cramps and - fullness, constipation, diarrhoea, dyspepsia, heartburn, nausea, vomiting, halitosis, belching, flatulence and dry mouth.

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

Reporting of side effects

If you experience side effects, talk to your doctor, pharmacist or other healthcare practitioner. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA'spublications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR.

5. How to store EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR

- Store all medicines out of reach of children.
- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Keep in original packaging until use.
- Close cap firmly after use.
- Do not refrigerate.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR contains

Active Ingredients	Per 2,5 ml	Per maximum daily dose (15 ml)
<i>Hedera helix</i> (English ivy) [leaf, 6:1 extract providing 17,5 mg DHE**]	2,9 mg	17,5 mg
<i>Matricaria chamomilla</i> (chamomile) [flower, 4:1 extract providing 4 mg DHE**]	1 mg	6 mg

**Dried Herb Equivalent.

Contains per 2.5 ml: sugar alcohol (sorbitol) 750 mg and (glycerine) 150 mg: sweetener: (sucralose) 0.5 mg: preservatives: potassium sorbate 0.16% (m/v) and sodium benzoate (0.15% m/v). No sugar, tartrazine or alcohol.

What EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR looks like and contents of the pack

EXPECTAMED PAEDIATRIC COUGH SYRUP JUNIOR is a light pink liquid, available in a amber glass bottle with a white cap. It contains 100 ml liquid & 200 ml liquid in a printed unit carton, that includes a patient information leaflet.

Holder of Certificate of Registration

Nativa (Pty) Ltd
260 Cradock Avenue, Lyttelton, Centurion, 0157, Gauteng, South Africa
Tel: +27 (0) 12 664 7110
Customer care line: 0860 628 482
Email: health@nativa.co.za
Website: www.nativa.co.za

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