

PATIENT INFORMATION LEAFLET: ACTORVIT™ KIDDY SYRUP

Vitamin A, Vitamin B₁, Vitamin B₂, Vitamin B₃, Vitamin B₅, Vitamin B₆, Vitamin B₁₂, Vitamin C, Vitamin D₃, Calcium, Iron, Lysine.

Sugar free.

Contains sweetener: Sorbitol 70 % (non crystallising): 500 mg/ml; Sodium saccharin: 2 mg/ml.

Complementary Medicine (Health Supplement).

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

Health supplements are intended only to complement health or supplement the diet.

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

ACTORVIT KIDDY SYRUP is available without a doctor's prescription, for you to maintain your child's health.

Nevertheless, you still need to use ACTORVIT KIDDY SYRUP carefully to get the best results.

- Keep this leaflet. You may need to read it again.
- Do not share ACTORVIT KIDDY SYRUP with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What ACTORVIT KIDDY SYRUP is and what it is used for
2. What you need to know before you use ACTORVIT KIDDY SYRUP
3. How to use ACTORVIT KIDDY SYRUP
4. Possible side effects
5. How to store ACTORVIT KIDDY SYRUP
6. Contents of the pack and other information

1. What ACTORVIT KIDDY is and what it is used for

ACTORVIT KIDDY SYRUP is a multi-vitamin, mineral and amino acid health supplement for children and contains vitamins and minerals which help meet children's daily nutritional needs. Vitamins and minerals help children develop properly and keep their bodies functioning optimally. Each vitamin and mineral plays a vital role and has a particular function in the body. Refer to the table below for a brief summary of what these functions are.

VITAMIN / MINERAL	FUNCTION
Vitamin A	<p>Contributes to the maintenance of eyesight, skin, membranes and immune function.</p> <p>Contributes to the development and maintenance of night vision.</p> <p>Contributes to the development and maintenance of bones and teeth.</p> <p>A factor in the maintenance of good health.</p>
B Vitamins	<p>The B vitamins complement each other and work best when taken together.</p>
Vitamin B ₁	<p>Helps to metabolise carbohydrates, fats and proteins.</p> <p>Contributes to normal growth.</p> <p>A factor in the maintenance of good health.</p>
Vitamin B ₂	<p>Helps to metabolise carbohydrates, fats and proteins.</p> <p>Contributes to tissue formation.</p> <p>A factor in the maintenance of good health.</p>
Vitamin B ₃	<p>Helps to metabolise carbohydrates, fats and proteins.</p> <p>Contributes to normal growth and development.</p> <p>A factor in the maintenance of good health.</p>
Vitamin B ₅	<p>Helps to metabolise carbohydrates, fats and proteins.</p> <p>Contributes to tissue formation.</p> <p>A factor in the maintenance of good health.</p>
Vitamin B ₆	<p>Helps to metabolise carbohydrates, fats and proteins.</p> <p>Contributes to tissue formation.</p> <p>A factor in the maintenance of good health.</p>
Vitamin B ₁₂	<p>Helps to metabolise carbohydrates, fats and proteins.</p> <p>Contributes to normal red blood cell formation.</p> <p>A factor in the maintenance of good health.</p>
Vitamin C	<p>Helps to metabolise fats and proteins.</p> <p>Helps in the development and maintenance of bones, cartilage, teeth and gums.</p> <p>Helps in connective tissue formation.</p> <p>Helps in wound healing.</p> <p>An antioxidant for the maintenance of good health.</p> <p>A factor in the maintenance of good health.</p>

Vitamin D ₃	<p>For the maintenance of healthy bones and teeth.</p> <p>Helps the body utilise calcium which is necessary for the normal development and maintenance of strong bones and teeth.</p> <p>Helps in the development and maintenance of bones and teeth.</p> <p>Helps in the absorption and use of calcium and phosphorous.</p> <p>A factor in the maintenance of good health.</p>
Calcium	<p>Contributes to the development and maintenance of bones and teeth.</p> <p>A factor in the maintenance of good health.</p>
Iron	<p>Helps to form red blood cells and helps in their proper function.</p> <p>A factor in the maintenance of good health.</p>
Lysine	<p>Amino-acids are the building blocks of life and constituents of living cells essential for growth and repair of tissues. Essential amino acids cannot be made by the body. As a result, they must come from an external nutrient source.</p>

2. What you need to know before you use ACTORVIT KIDDY SYRUP

Do not give ACTORVIT KIDDY SYRUP if any of the following conditions are present:

- Hypersensitivity (allergy) to any of the ingredients in ACTORVIT KIDDY SYRUP.
- Disturbances of calcium metabolism, such as hypercalciuria (excessive calcium in the urine) and hypercalcaemia (excessive blood calcium levels).
- High levels of vitamin D in the body or simultaneous intake of other products containing vitamin D.
- High levels of iron in their body. Preparations containing iron and vitamin C should not be taken in the presence of haemochromatosis and haemosiderosis (high levels of iron in the body).
- Blood disorders and bleeding disorders in which the blood does not clot normally.
- Bowel obstruction.
- Leber's Disease (loss of vision).
- Wernike-Korsakoff's syndrome (a brain disorder).
- Renal (kidney) or hepatic (liver) insufficiency.
- Calcium based kidney stones.
- Phenylketonuria, which is an inherited inability to metabolise phenylalanine, which is an essential amino acid.
- Hypercalcaemia.

Consult your doctor, pharmacist or other health care professional if you have any queries.

Take special care with ACTORVIT KIDDY SYRUP:

- If your child has anaemia as a result of vitamin B₁₂ deficiency. ACTORVIT KIDDY SYRUP is not intended to be used to help with this condition.
- Vitamin D should be given with caution to infants, as they may be more sensitive to its effects.
- Vitamin B₃ should be given with caution to children with peptic ulcers.
- Vitamin C should be given with caution to children with diabetes mellitus (high blood sugar).
- The indicated daily dose should not be exceeded.

Other medicines and ACTORVIT KIDDY SYRUP:

Always tell your healthcare professional if your child is taking any other medicine. This includes all complementary or traditional medicines.

ACTORVIT KIDDY SYRUP contains vitamin B₆, which may decrease the effectiveness of L-Dopa, a medicine used to treat Parkinson's Disease.

Pregnancy and breastfeeding:

ACTORVIT KIDDY SYRUP is indicated for use in children. Regardless of this please note the following:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before using ACTORVIT KIDDY SYRUP.

If you are or are planning to become pregnant, you should avoid supplements containing more than a daily dose of 5000 IU Vitamin A. Even though ACTORVIT KIDDY SYRUP contains less than 5000 IU per dose, the total daily quantity of vitamin A that you may take might be exceeded if ACTORVIT KIDDY SYRUP is taken together with a high vitamin A diet.

The pineapple flavouring in ACTORVIT KIDDY SYRUP contains dextrose:

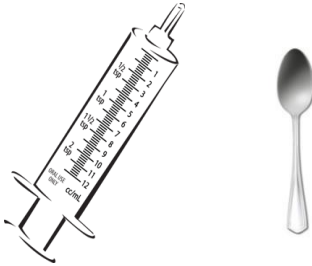
Dextrose may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to give ACTORVIT KIDDY SYRUP

Always give ACTORVIT KIDDY SYRUP exactly as described in this leaflet or as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.



- Shake well before use.



- Using a clean teaspoon or syringe, follow the instructions indicated below. The amount of ACTORVIT KIDDY SYRUP to give your child depends on their age. Do not exceed the recommended dosage.

Children 1 to 3 years: 1,25 ml ($\frac{1}{4}$ teaspoon) once daily.

Children 4 to 8 years: 2,5 ml ($\frac{1}{2}$ teaspoon) once daily.

Children 9 to 13 years: 5 ml (1 teaspoon) once daily.



- Close the bottle tightly after use.

If you give more ACTORVIT KIDDY SYRUP than you should:

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

If you forget to give ACTORVIT KIDDY SYRUP:

If you forget to give a dose, give it as soon as you remember it, then go back to your regular dosing schedule.

Do not give a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

ACTORVIT KIDDY SYRUP can have side effects.

Not all side effects reported for ACTORVIT KIDDY SYRUP are included in this leaflet.

Should your child's general health worsen or if your child experiences any untoward effects while taking ACTORVIT KIDDY SYRUP, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following should happen, stop giving ACTORVIT KIDDY SYRUP to your child and tell your doctor immediately or go to the casualty department at your nearest hospital.

- Itching or rash
- Difficulty breathing
- Swelling of the face, lips, tongue or throat

These are all very serious side effects. If your child has had them, he/she may have had a serious reaction to ACTORVIT KIDDY SYRUP.

Your child may also experience the following mild side effects:

- Yellow discolouration of urine (due to vitamin B₂)
- Stools may appear darker or black in colour (due to iron)
- Occasional stomach complaints, stomach pain, nausea and vomiting, diarrhoea, constipation and headache.

Most side effects occur when your child takes more ACTORVIT KIDDY SYRUP than they should. It is therefore important to ensure that you give your child ACTORVIT KIDDY SYRUP as directed.

If you notice side effects that are not described in this leaflet, you should tell your doctor or pharmacist.

Reporting of side effects:

If your child experiences side effects, talk to your doctor or pharmacist.

You can report side effects to Actor Pharma (Pty) Ltd via email:

pharmacovigilance@actorpharma.co.za or telephonically on 011 312 3812.

You can also report side effects to 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 ACTORVIT KIDDY SYRUP.

5. How to store ACTORVIT KIDDY SYRUP

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store in the original packaging in a dry place at or below 25 °C. Protect from light.

Do not use after the expiry date stated on the packaging.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ACTORVIT KIDDY SYRUP contains:

The active substances are:

	Quantity per dosage unit (mg/5 ml)
<u>Vitamins:</u>	
Vitamin A palmitate 250 (Vitamin A)	2000 IU
Thiamine hydrochloride (Vitamin B ₁)	2,00 mg
Riboflavin-5-phosphate sodium (Vitamin B ₂)	1.500 mg
Niacinamide (Vitamin B ₃)	25.00 mg
Calcium-D-pantothenate (Vitamin B ₅)	2.250 mg
Pyridoxine hydrochloride (Vitamin B ₆)	1,000 mg
Vitamin B ₁₂ 0.1% W.S (Vitamin B ₁₂)	0.001 mg
Ascorbic acid (Vitamin C)	30,00 mg
Dry Vitamin D ₃ 100 CWS (Vitamin D ₃)	200 IU
<u>Minerals:</u>	
Calcium gluconate (Calcium)	311 mg
Ferrous gluconate (Iron)	6,50 mg
Magnesium sulphate heptahydrate (Magnesium)	4.120 mg
<u>Amino acids:</u>	
L-Lysine	75,00 mg

Other ingredients are:

Sweetening agents: Sodium saccharin, Sorbitol 70 % (non-crystallising).

Flavouring agent: Pineapple flavour.

Preservative: Sodium benzoate 0,2 % m/v.

Others: Citric acid anhydrous, purified water.

What ACTORVIT KIDDY SYRUP looks like and contents of the pack:

ACTORVIT KIDDY SYRUP is a viscous (thick), sweet, pineapple –flavoured syrup.

ACTORVIT KIDDY SYRUP is available in a 200 ml amber glass bottle.

Name and address of Applicant:

Actor Pharma (Pty) Ltd¹
Unit 7, Royal Palm Business Estate
646 Washington Street
Halfway House, Midrand, 1685

TM: ACTORVIT is a trademark of Actor Pharma (Pty) Ltd

¹ Company registration number: 2008/008787/07

AVIT/PIL/01/04.2020