

PACKAGE LEAFLET: INFORMATION FOR THE USER

Abidec

MULTIVITAMIN ORAL DROPS SOLUTION

Read all of this leaflet carefully before you start using this medicine because it contains important information. This medicine is for your child.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Abidec Multivitamin Drops are and what they are used for
2. What you need to know before you use Abidec Multivitamin Drops
3. How to use Abidec Multivitamin Drops
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6. Contents of the pack and other information

1. What Abidec Multivitamin Drops are and what they are used for

Abidec Multivitamin Drops contains 1333 IU retinol (as vitamin A palmitate), 400 IU ergocalciferol, 0.4 mg thiamine hydrochloride, 0.8 mg riboflavin sodium phosphate, 0.8 mg pyridoxine hydrochloride, 8 mg nicotinamide, and 40 mg ascorbic acid in each 0.6 ml dose.

Abidec Multivitamin Drops are used to prevent vitamin deficiencies in babies and children up to 12 years old. It is not designed for adults. This medicine contains seven essential vitamins that a child or baby needs to grow and keep healthy.

2. What you need to know before you use Abidec Multivitamin Drops

Do not use Abidec Multivitamin Drops

if your child is allergic to peanut oil because Abidec Multivitamin Drops contain arachis oil (peanut oil).

- if your child is allergic to soya.
- if your child is allergic to any of the active substances (listed above in section 1) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Abidec Multivitamin Drops.

When prescribing Abidec Multivitamin Drops, as with all multivitamin preparations, allowance should be made for vitamins obtained from other sources.

While children are taking Abidec Multivitamin Drops no other vitamin supplement containing vitamins A and D should be taken unless under medical supervision.

This multivitamin supplement should not be given to babies who are receiving more than 500mls of formula milk per day to avoid exceeding the safe upper limit of Vitamin A.

Excessive dosage of vitamin A and D may lead to hypervitaminoses. Due allowance should always be made for intake of these vitamins from other sources.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. May be harmful to the teeth.

Other medicines and Abidec Multivitamin Drops

Your child can be given Abidec Multivitamin Drops if he or she is taking other medicines because the drops don't interfere with other medicines.

However, do not give your child other vitamin preparations at the same time.

Abidec Multivitamin Drops contains arachis oil (peanut oil)

Abidec Multivitamin Drops contains arachis oil (peanut oil). If your child is allergic to peanut or soya, do not use this medicinal product.

Abidec Multivitamin Drops contains sucrose

If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before using this medicinal product. May be harmful to the teeth – follow the instruction to place the drops at the back of the tongue.

Abidec Multivitamin Drops contains sodium

This medicine contains less than 1mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to give Abidec Multivitamin Drops

Always use 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.

For oral use. Give Abidec Multivitamin Drops as a daily dose using the syringe provided.

The recommended dose for children under the age of 1 year: give 0.3ml (higher mark on syringe) on the back of the tongue. Maximum daily dose: 0.3ml.

The recommended dose for children aged 1-12 years: give 0.6ml (lower mark on syringe) on the back of the tongue. Maximum daily dose: 0.6ml.

Wash and dry the syringe thoroughly after use (not in a steam steriliser). Reseal the bottle with original cap after each use.

If you use more Abidec Multivitamin Drops than you should

The syringe provided helps you give the correct dose to your child. Should your child have too much medicine tell your doctor even though it is unlikely that it will cause any harm.

If you forget to use Abidec Multivitamin Drops

Give a dose as soon as you remember unless it is nearly time for the next dose. Do not give a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Abidec Multivitamin Drops contain peanut oil (arachis oil) which may cause an allergic reaction (such as itching, swelling of the tongue, eyes, lips and hands). Do not use this product if you know or suspect your child is allergic to peanuts or soya.

If your child feels ill after using Abidec Multivitamin Drops, or you notice any unusual or unexpected symptoms, tell your doctor or go to the Accident and Emergency department of your nearest hospital.

Reporting of side effects

If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance; Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Abidec Multivitamin Drops

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after "EXP". The expiry date refers to the last day of that month. If the expiry date has passed, take the product back to your pharmacist for safe disposal.

Do not store above 25°C. Keep the bottle in the outer carton to protect from light. Once opened, use within 4 weeks. Store upright and keep bottle tightly closed.

Do not throw away any medicines via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Abidec Multivitamin Drops contain

The active substances in each 0.6 ml dose are:

Retinol (as vitamin A Palmitate) 1333 IU, Ergocalciferol (Vitamin D2) 400 IU, Thiamine Hydrochloride (Vitamin B1) 0.4 mg, Riboflavin Sodium Phosphate (Vitamin B2) 0.8 mg, Pyridoxine Hydrochloride (Vitamin B6) 0.8 mg, Nicotinamide 8mg and Ascorbic Acid (Vitamin C) 40 mg.

The other ingredients are:

Sodium hydroxide, sucrose, refined peanut oil, DL- α -tocopherol, polysorbate 60 and purified water.

What Abidec Multivitamin Drops looks like and contents of the pack

Abidec Multivitamin Drops is a yellow/brown liquid in a 25ml bottle or in a pack containing 2 x 25ml bottles, but all pack sizes may not be marketed. This colour can become cloudy or darken but can still be used if this happens within 4 weeks of opening and if it has not passed the expiry date (printed on bottle label and carton). The colour, smell and flavour of the product are the natural colour, smell and flavour of the vitamins.

Marketing Authorisation Holder

Chefaro Ireland DAC, The Sharp Building,
Hogan Place, Dublin 2, Ireland. Send all enquiries to this address.

Manufacturer

Pharmaceutical Works POLPHARMA S.A., Medana Branch in Sieradz, 10 W. Łokietka St, 98-200 Sieradz,
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