

Betamethasone 500 microgram Soluble Tablets

**Package leaflet:
Information for the user**

Betamethasone 500 microgram soluble tablets

Betamethasone sodium phosphate

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- **Betamethasone Soluble Tablets are a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Do not stop taking this medicine** without talking to your doctor – you may need to reduce the dose gradually.
- **Betamethasone Soluble Tablets can cause side effects in some people** (see section 4). Some problems such as mood changes (feeling depressed or 'high') or stomach problems can happen straight away. If you feel unwell in any way, keep taking your medicine, **but see your doctor straight away**.
- **Some side effects only happen after weeks or months**. These include weakness of arms and legs or developing a rounder face (see section 4).
- **If you take it for more than three weeks, you will get a blue 'steroid card'**: always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chickenpox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chickenpox or shingles, see your doctor straight away.

What is in this leaflet

1. What Betamethasone Soluble Tablets are and what they are used for
2. What you need to know before you take Betamethasone Soluble Tablets
3. How to take Betamethasone Soluble Tablets
4. Possible side effects
5. How to store Betamethasone Soluble Tablets
6. Contents of the pack and other information

1. What Betamethasone Soluble Tablets are and what they are used for

Betamethasone 500 microgram Soluble Tablets (called Betamethasone Soluble Tablets in this leaflet) contains the active substance betamethasone. This belongs to a group of medicines called corticosteroids or steroids. Steroids are used to treat many different conditions including:

- asthma
- severe allergic reactions
- rheumatoid arthritis
- autoimmune diseases such as systemic lupus erythematosus (SLE) and polyarteritis nodosa
- inflammatory conditions of the skin, kidney (such as acute interstitial nephritis or minimal change nephrotic syndrome), bowels (such as ulcerative colitis and Crohn's disease) and heart
- some connective tissue diseases
- certain conditions of the blood
- some types of cancer, such as malignant lymphoma.

Corticosteroids are also used to help prevent organ transplant rejection following organ transplant surgery.

2. What you need to know before you take Betamethasone Soluble Tablets

- Do not take Betamethasone Soluble Tablets:**
- if you have an infection and you are not taking antibiotics
 - if you are allergic to betamethasone or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions

Talk to your doctor before taking this medicine if you have:

- recently had a heart attack
- an underactive thyroid
- myasthenia gravis causing weak muscles
- had contact recently with a person with chickenpox, shingles or measles or have had any of these diseases recently yourself. Taking this product may make the disease worse.
- recently been, or are due to be, vaccinated or have had an ulcer in your stomach or gut
- or have had tuberculosis (TB)
- epilepsy (fits)
- or have had severe mental illness
- hypertension (high blood pressure)
- osteoporosis (thinning of the bones). Post-menopausal women are particularly at risk of this
- ever suffered from muscle wasting due to corticosteroids
- liver, kidney or heart disease
- pheochromocytoma (a tumour of the adrenal gland)
- experienced blurred vision or other visual disturbances.

Contact your doctor if you experience blurred vision or other visual disturbances.

Talk to your doctor before taking this medicine if you or a member of your family have:

- **ever had severe depression or manic depression** (bipolar disorder). This includes having had depression before or while taking steroid medicines like Betamethasone Soluble Tablets
- glaucoma (raised eye pressure)
- diabetes

Chickenpox, shingles or measles

Before taking Betamethasone Soluble Tablets talk to your doctor if you have recently been in contact with a person with chickenpox, shingles or measles or have had any of these diseases recently yourself. While taking Betamethasone Soluble Tablets avoid contact with anyone who has chicken pox, shingles or measles. **Contact your doctor immediately** if you believe you have come into contact with anyone with these diseases while taking your tablets.

Mental problems while taking Betamethasone Soluble Tablets

Mental health problems can happen while taking steroids like Betamethasone Soluble Tablets (see also section 4).

- these illnesses can be serious
- usually they start within a few days or weeks of starting the medicine
- they are more likely to happen at high doses
- most of these problems go away if the dose is lowered or the medicine is stopped. However, they might need treatment.

Children and adolescents

Betamethasone can suppress growth in children and adolescents. Your doctor will make sure your child's treatment is kept to the shortest time and the lowest dose required to treat their condition.

Other medicines and Betamethasone Soluble Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines without prescription.

- **Some medicines may increase the effects of betamethasone or may be affected by betamethasone.** Your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, zalcitabine), insulin or oral antidiabetic drugs.
- **Medicines for high blood pressure;**
- **Water tablets** (diuretics);
- **Medicines for thinning the blood** e.g. warfarin;
- **Non-steroidal anti-inflammatory drugs** e.g. ibuprofen;
- **Salicylates** e.g. aspirin;
- **Medicines for myasthenia gravis** called anticholinesterases;
- **Medicines for the heart** called cardiac glycosides;
- **Acetazolamide** (used to treat glaucoma);
- **Rifampicin and rifabutin** (antibiotics for tuberculosis) and **ephedrine**;
- **Carbamazepine, phenytoin, primidone, phenobarbitone and aminoglutethimide** for epilepsy
- **Carbenoxolone** (an ulcer healing drug), **theophylline** (used to treat asthma and other breathing difficulties) and **amphotericin B** (antifungal)
- **Oral contraceptive** (the pill)
- **Mifepristone** (anti-progesterone)
- **Somatotropin** (growth hormone)
- **Vecuronium** and other muscle relaxants
- **Fluoroquinolones** (used for some infections)
- **Quetiapine** (improves symptoms of some mental illnesses)
- **Tretinoin** (used to treat bad acne)

Betamethasone Soluble Tablets may also affect the results of gall bladder X-ray procedures.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Taking steroids often or for a long time during pregnancy can slow the baby's growth in the womb or may temporarily affect the baby's heart and body movements.

The baby may also make less of its own steroid after birth, but this rarely causes any problems. If you become pregnant whilst taking this medicine, please tell your doctor but **DO NOT stop taking the tablets unless told to do so** (see section 3).

Breastfeeding

Betamethasone may pass into breast milk. Ask your doctor or pharmacist for advice before taking this medicine.

Fertility

It is not known if steroids affect fertility.

Important information about some of the ingredients of Betamethasone Soluble Tablets

- This medicine contains:
- **Sodium:** This medicine contains less than 1 mmol sodium (23 mg) for a dose of one tablet that is to say essentially 'sodium-free'. If your dose is between 2-30 tablets this medicine contains 41-205 mg sodium (main component of cooking/table salt) in each dose. This is equivalent to 1.71% to 0.54% of the UK recommended maximum daily dietary intake of sodium for an adult.
 - **Sodium benzoate:** This medicine contains 4 mg sodium benzoate in each tablet which may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take Betamethasone soluble tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not or you are not sure, ask your doctor or pharmacist.

You may have been given a **steroid card** which also tells you how many tablets to take each day (see section 6).

- It is best to dissolve the tablets in water and drink immediately.
- Your tablets can also be swallowed whole
- If you need to take half a tablet you should break it in half along the scored line on the tablet. Do not keep the remaining half tablet

Adults

Short term treatment:

- 4 to 6 tablets (2000 - 3000 micrograms) daily for the first few days.
- Your doctor may reduce the daily dose by 1/2 or 1 tablet (250 - 500 micrograms) every two to five days, depending upon the response.

Rheumatoid arthritis:

- 1 to 4 tablets (500 - 2000 micrograms) daily;
- For long-term treatment the dose may be lower.

Most other conditions:

- 3 to 10 tablets (1500 - 5000 micrograms) daily for one to three weeks;
- Your doctor may then gradually reduce this to a lower dose;
- Larger doses may be needed for mixed connective tissue diseases and ulcerative colitis.

Use in children and adolescents

- Your doctor will usually how much to give your child. This will usually be a proportion of the adult dose.

While you are taking this medicine, your doctor may ask you to have check-ups. These are to make sure that your medicine is working properly and that the dose you are taking is right for you.

If you take more Betamethasone Soluble Tablets than you should

If you, or your child, accidentally take too much, immediately contact the nearest hospital casualty department or your doctor. Take this leaflet with you. This is so the doctor knows what you have taken.

If you forget to take Betamethasone Soluble Tablets

If you forget a dose, take the next dose as soon as you remember. **Do not take a double dose** to make up for a forgotten dose.

If you stop taking Betamethasone Soluble Tablets

It is very important that you do not suddenly stop taking Betamethasone Soluble Tablets, even if you feel better or are suffering from a side effect, unless your doctor tells you to.

Your doctor will tell you how to stop taking Betamethasone Soluble Tablets .

If you stop taking your medicine suddenly, you may suffer from some of the following side effects: fever, joint and muscle pain, itching eyes, nose or skin, mood changes, loss of weight, dizziness, headaches or fainting. In extreme cases, this can be fatal.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Serious including betamethasone can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like betamethasone.

Talk to your doctor or go to hospital straight away if you

- feel depressed, including thinking about suicide.
- feel high (mania) or your mood goes up and down.
- feel anxious, are having problems sleeping, difficulty in thinking or being confused and losing your memory.
- feel, see or hear things which do not exist. Have strange and frightening thoughts, changing how you act or having feelings of being alone.

Talk to your doctor or go to hospital straight away if you

- have an allergic reaction. Signs of an allergic reaction include: a rash, problems swallowing or breathing, swelling of the lips, face, throat or tongue.
- have blistering or bleeding of the skin, including around your lips, eyes, mouth, nose and genitals. You may have flu-like symptoms and fever. This is called "Stevens-Johnson syndrome".

Other side effects:

Frequency not known (cannot be estimated from the available data)

- High doses taken for a long time or repeated short courses, can lead to side effects such as:
- irregular menstrual periods in women
 - suppression of growth in adolescents and children
 - changes in blood sugar, salt or protein levels
 - extra hair growth and/or weight gain, increased sweating or increases in appetite

- increased levels of cholesterol in your blood
- increased likelihood and severity of infection, including recurrence of tuberculosis (TB) if you already have TB
- wasting of muscles, thinning of the bones (osteoporosis) or fractures, breaking of tendons and breakdown of the bone due to lack of blood supply
- water retention (which may cause a bloated feeling) or higher blood pressure (symptoms may include headaches) or changes in blood chemistry due to loss of potassium
- if you have recently had a heart attack, betamethasone can cause a serious complication of the heart, where the tissues weaken
- mood changes, depression, sleep problems or worsening of epilepsy or schizophrenia if you already have either of these problems
- in children - throbbing headache which may be worse when you wake up, cough or with sudden movement, patchy vision with blind spots and possible lack of colour vision due to a build up of pressure in your head
- pressure in the eye (glaucoma), cataract, worsening of viral or fungal diseases, thinning of the cornea or sclera (the outer membrane of the eye), headaches, blurred vision
- heartburn or indigestion, hiccups, nausea, bloating of the abdomen, stomach ulcers which may bleed, oesophageal ulcer, thrush in the mouth or throat or pains in your stomach
- bruising, skin does not heal, abscesses, acne, rashes, thinning of the skin, prominent veins, changes in skin colour or blistering of the skin, mouth, eyes and genital
- blood clots or blood disorders or heart failure
- blurred vision

Additional care should be taken if this medicine is given to elderly patients, as side effects may be more serious.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Betamethasone Soluble Tablets

Store below 25°C. Store in the original package to protect from light and moisture.

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 after "EXP". The expiry date refers to the last day of that month.

Do not dispose of any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

- What Betamethasone Soluble Tablets contain**
- Each tablet contains 500 micrograms of the active substance, betamethasone, as betamethasone sodium phosphate.
 - The other ingredients are: sodium hydrogen carbonate (E500), disodium hydrogen citrate (E331), povidone K30 (E1201), sodium saccharin (E954), erythrosine (E127) and sodium benzoate (E211).

What Betamethasone Soluble Tablets look like and contents of the pack

The tablets are round, pink tablets scored on one side with R0.5 embossed on the other side.

They are supplied in blister strips of 10 tablets in cartons containing 100 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
ROMA Pharmaceuticals Limited
Gibraltarr House
Crown Square
Centrum 100
Burton-upon-Trent
DE14 2WE
Email: medinfo@romapharma.co.uk

Manufacturer
RAFARM SA
Thesi Pousi-Xatzi Agiou Louka,
Paiania Attiki,
19002, PO Box 37,
Greece

This leaflet was last revised in December 2021

Carrying a steroid card

If your doctor asks you to carry a steroid card, be sure to keep it with you always. Show it to any doctor, dentist, nurse or midwife or anyone else who is giving you treatment. Even after your treatment has finished tell any doctor, dentist, nurse, midwife or anyone else who is giving you treatment that you have had steroid treatment. A steroid card may be obtained from your doctor, pharmacist or local Family Health Service Authority. In Scotland, steroid cards are available from the Scottish Office of Home and Health.