

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

MEDITROL

Calcitriol BP 0.25 mcg

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

- a) What MEDITROL is and what it is used for
- b) Before you take MEDITROL
- c) How to take MEDITROL
- d) Possible side effects
- e) How to store MEDITROL
- f) Further information

a) WHAT MEDITROL IS AND WHAT IT IS USED FOR

Meditrol contains a medicine called calcitriol. This belongs to a group of medicines called ‘vitamin D metabolites’.

Meditrol is used to treat the following:

- Calcium deficiency (hypocalcemia) and Bone disease in people with kidney problems (renal osteodystrophy).
- Weakening of the bones in women after the menopause (change of life). This is also known as post-menopausal osteoporosis.
- Calcium deficiency (hypocalcemia) in patients with hypoparathyroidism (underactive parathyroid glands).
- Rickets (type of bone disease).

Meditrol works by making your body absorb more calcium from your diet. This helps to form healthy bones and reduce bone damage.

b) BEFORE YOU TAKE MEDITROL

Do not take MEDITROL:

if you are allergic (hypersensitive) to:

- Calcitriol or any of the other ingredients of this medicine (listed in section 6).
- Other ‘vitamin D metabolite’ medicines (used to treat bone disease). These include alfacalcidol and colecalciferol.

Do not take MEDITROL if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking MEDITROL.

Do not take MEDITROL if:

- You have high levels of calcium in your blood (hypercalcaemia).
- You have extra deposits of calcium in your body (metastatic calcification).
- You are unwell because of high levels of vitamin D in your body.

Do not take MEDITROL if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking MEDITROL.

Warnings and precautions

Talk to your doctor or pharmacist before taking MEDITROL if:

- You are finding it difficult to move about (for example, after an operation).
- You have kidney problems (the doctor may need to monitor the phosphate levels in your blood and diet).

Other medicines and MEDITROL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because MEDITROL can affect the way some medicines work. Also some other medicines can affect the way MEDITROL works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other medicines containing vitamin D.
- Diuretics, also called ‘water tablets’ (used to treat high blood pressure). These include bendroflumethiazide, chlortalidone and indapamide.
- Medicines like digoxin or digitoxin (used to treat heart disease).
- Medicines containing magnesium, such as antacids (used to treat indigestion).
- Steroid medicines, such as hydrocortisone, prednisolone and dexamethasone.
- Cholestyramine, or other ‘ion-exchange resins’ (used to treat high levels of cholesterol in your blood).
- Phosphate (the doctor may need to monitor phosphate levels in your blood).

Also tell your doctor or pharmacist if you have taken a medicine containing vitamin D over the last few months that has long-lasting effects. These medicines include ergocalciferol and colecalciferol.

MEDITROL with food and drink

- Do not take any vitamin or food supplements that contain vitamin D while you are taking MEDITROL.
- Do not eat food which has vitamin D added (food which is ‘fortified’ with vitamin D) while you are taking MEDITROL.
- It is very important to keep to any diet that your doctor has given to you.
- If you change how much calcium or vitamin D you have in your diet this can increase the risk of side effects (for example, if you eat more dairy products like milk and cheese, or take vitamins without your doctor knowing).

- Drink plenty of fluids (such as water) as it is important not to become dehydrated. This does not apply if you have kidney problems.

Pregnancy and breast-feeding

- Talk to your doctor before taking MEDITROL if you are pregnant, think you are pregnant, or plan to get pregnant. Your doctor will then decide if you should take MEDITROL.
- You can take MEDITROL if you are breast-feeding. However, your doctor will take blood samples from you and your child to check that there are no unwanted effects.

Driving and using machines

MEDITROL is not likely to affect you being able to drive or use any tools or machines.

MEDITROL contains sorbitol

MEDITROL contains sorbitol, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. How to take MEDITROL

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

Swallow the capsules whole with a little water.

While you are taking MEDITROL, your doctor will want you to have regular blood tests to check that the level of calcium in your blood does not get too high.

The effectiveness of MEDITROL therapy is based on the assumption that each patient is receiving an adequate daily intake of calcium.

To ensure that you receive an adequate daily intake of calcium, your doctor may either prescribe a calcium supplement or instruct appropriate dietary measures. Your doctor may monitor your blood levels of calcium and phosphorus.

Be sure to drink plenty of fluids to maintain good hydration, important during MEDITROL treatment.

Usual adult dose:

Dosage is based on your medical condition and response to therapy. Your doctor may start you on a low dose and adjust the dose slowly to find the best dose for you. Follow your doctor's directions carefully.

Bone disease in people with kidney problems(renal osteodystrophy)

- The usual starting dose for adults and elderly people is one 0.25 microgram capsule once a day.
- After 2 to 4 weeks your doctor may start increasing your dose slowly by 0.25 microgram at a time.
- Eventually, depending on your blood test results, your doctor may need to adjust your dose again. He or she may ask you to take MEDITROL two or three times a week instead of every day. The maximum dose each week is 12 micrograms.

Bone disease after the menopause (post-menopausal osteoporosis)

- The usual dose for adult and elderly women is one 0.25 microgram capsule twice a day.

If you take more MEDITROL than you should

- If you take more MEDITROL than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.
- If you take too many capsules, you may get too much calcium in your blood (hypercalcaemia). The signs include loss of appetite, weight loss, feeling sick, being sick, constipation, headache and feeling sluggish, drowsy or weak.

If you forget to take MEDITROL

- If you forget to take a dose, skip the missed dose. Then take your next dose as normal.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking MEDITROL

Do not stop taking MEDITROL without talking to your doctor. This is because weakness of your bones needs long term treatment.

If someone else takes your MEDITROL capsules by mistake, they should talk to a doctor or go to a hospital straight away.

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

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4. Possible side effects

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

The following side effects may happen rarely with this medicine:

High levels of calcium in your blood

- The signs include loss of appetite, weight loss, feeling sick, being sick, headache and feeling sluggish, drowsy or weak.
- Very high levels of calcium in your blood may lead to high temperature (fever), feeling thirsty, dehydration, passing more water than normal, wetting the bed, constipation, stomach pain, blockage of the bowel and an uneven heart beat. There may be infections in the bladder and normal growth may stop.
- Occasionally, mental problems may occur. Also there may be deposits of calcium in areas other than your bone (for example, in your kidneys as 'kidney stones'). Your doctor may change your dose of MEDITROL if this happens.

Kidney

- Changes in how well your kidney is working (shown by blood tests).

Allergic reactions

- The signs can include itchy skin, skin rashes and reddening of the skin (which may be severe).

If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get 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 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.

c) **HOW TO STORE MEDITROL**

Keep out of the reach and sight of children.

Store below 30°C in a dry place, away from direct sunlight.

Do not use this medicine after the expiry date (EXP) stated on the pack and blister.

Return left over capsules to your pharmacist. Only keep them if your doctor tells you to.

d) **FURTHER INFORMATION**

What MEDITROL contains:

The active pharmaceutical ingredient is Calcitriol BP 0.25 mcg

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The other ingredients as follows;

Inactive ingredient:

Butylated Hydroxyanisole, Butylated Hydroxytoluene , Fractionated Coconut Oil.

Capsule shell:

Gelatin, Glycerin, Sorbitol 70% solution, Purified water, Iron oxide yellow, Iron oxide red, Titanium dioxide (Red color), Titanium dioxide (White color).

What MEDITROL looks like and contents of the pack:

Pharmaceutical form: Clear, colourless, oily liquid, filled in 3 minim, oval, red and white, opaque soft gelatin shell capsules

Marketing Authorization Holder

MEGA LIFESCIENCES Public Company Limited

384 Moo 4, Soi 6, Bangpoo Industrial Estate,

Pattana 3 Road, Phraeksa, Mueang,

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This leaflet was prepared on {December/2023}.

