Calcort 6mg Tablets

Deltazacort

SANOFI

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1. What Calcort is and what it is used for

The name of your medicine is Calcort 6mg Tablets (called Calcort throughout this leaflet). Calcort is a steroid medicine. Their full name is glucocorticoids.

How Calcort works
• These corticosteroids occur naturally in the body, and help to maintain health and wellbeing.
• Boosting your body with extra corticosteroid (such as Calcort) is an effective way to treat various illnesses involving inflammation in the body.
• Calcort works by reducing this inflammation, which could otherwise go on making your condition worse.
• Calcort also works by stopping reactions known as autoimmune reactions. These reactions happen when your body’s immune system attacks the body itself and causes damage.
• You must take this medicine regularly to get maximum benefit from it.

Calcort can be used to:
• Treat inflammation including asthma, arthritis and allergies.
• Treat problems with your skin, kidney, heart, digestive system, eyes or blood.
• Treat problems where your body has growths (tumours).
• Suppress the immune system in transplant operations.

2. Before you take Calcort

Do not take this medicine and tell your doctor if:
• You are allergic (hypersensitive) to deflazacort or any of the other ingredients in these tablets (see Section 6. Further information). Signs of an allergic reaction include: a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.
• You have an infection that affects your whole body (systemic infection), which is not already being treated.
• You are having or have recently had any vaccinations with live viruses (see "vaccinations" below).

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

Take special care and check with your doctor before you take Calcort if:
• You have ever had severe depression or manic-depression (bipolar disorder).
• This includes having had depression before while taking steroid medicines like Calcort.
• Any of your close family has had these illnesses.
• You have or ever had mental problems such as depression or psychoses.

If any of the above applies to you, talk to a doctor before taking Calcort.

3. How to take Calcort

4. Possible side effects

5. How to store Calcort

6. Further information

Please read all of this leaflet carefully before you start taking this medicine.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

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

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not give it to others. It may harm them, even if their symptoms are the same as yours.

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

Your doctor may have given you this medicine for a long time. They could affect you severely. If you do come into contact with chickenpox or shingles, see your doctor straight away.

If you are allergic (hypersensitive) to deflazacort or any of the other ingredients in these tablets (see Section 6. Further information). Signs of an allergic reaction include: a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.

• You have an infection that affects your whole body (systemic infection), which is not already being treated.

• You are having or have recently had any vaccinations with live viruses (see "vaccinations" below).

• You have or ever had mental problems such as depression or psychoses.

If any of the above applies to you, talk to a doctor before taking Calcort.

Before you take Calcort

We have included warnings that summarise any possible side effects of Calcort that occur for more than 5% of patients.

Some side effects only happen after weeks or months. This can be because it takes time for your body to adapt to the medicine.

Some side effects are more likely to happen if you take this medicine for a long time.

Some side effects may return.

Some side effects may grow less than normal. (Not known: frequency cannot be estimated from the available data).

Some side effects may get serious or last longer than usual.

Some of the side effects are more likely to happen if you are elderly.

If you notice any of these problems talk to a doctor straight away.

Other side effects:
Please tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days.

Uncommon (affects 1 to 10 users in 1,000)
• Stomach or bowel problems such as feeling full or bloated, indigestion, heartburn or stomach pain.
• Increased thirst and needing to pass water more than usual. These could be signs of diabetes. If you are already diabetic, your doctor may prescribe more of your diabetes medicine to balance the effects of deflazacort. You should discuss this with your doctor.
• Raised blood pressure and increased water retention.
• Tiredness, confusion, muscle weakness or muscle cramps. This may be due to low levels of potassium in your body.
• Mood changes, difficulty in sleeping.
• If you have had tuberculosis (TB) in the past it may return.
• Skin problems such as acne, appearance of stretch marks.
• You may get infections more easily than usual.

Rare (affects 1 to 10 users in 10,000)
• Bleeding under the skin, redness.
• General muscle weakness or tiredness.

Not known (frequency cannot be estimated from the available data)
• Bones and tendons may break or tear more easily than usual. Also tendons may get inflamed and become painful.
• Irregular periods in women or they may stop altogether.
• Becoming dependent on deflazacort (also called psychological dependence).
• If you have schizophrenia your symptoms may get worse.
• Fungal infection such as thrush.
• Eye disease that causes detachment of the retina and bulging eyes.
• Eye problems such as glaucoma and cataracts can happen if you take this medicine for a long time.
• Eye infections (viral) may spread or return if you have had them in the past.

Blurred vision.
• Increase in the risk of clots forming in your blood.
• Blood problems such as leucocytosis.
• Injuries and cuts do not heal as quickly as usual.
• Noticeable blood vessels, thinning of the skin.
• Sudden or severe muscle weakness or tiredness following an operation.
• Some of the side effects are more likely to happen if you are elderly.

Children and teenagers taking this medicine may grow less than normal. (Not known: frequency cannot be estimated from the available data).

If you think this is happening to a child, tell your doctor.

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 further information on the safety of this medicine.

5. How to store Calcort

• Keep out of the sight and reach of children.
• Do not take 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.
• Keep this medicine below 25°C. Keep it in the environment.

6. Further information

What Calcort contains
Each tablet contains 6mg of the active substance, deflazacort.
The other ingredients are microcrystalline cellulose, lactose, maize starch and magnesium stearate.

What Calcort looks like and contents of the pack Calcort 6mg Tablets are round, white, uncoated tablets, marked with a cross on one face and a ‘6’ on the other face.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
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Manufacturer
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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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PACK. ITEM: 10,5 pt su 11 pt

Calcort 6mg Tablets
Delfazacort

Istruzioni

PACK. ITEM:

Nota: la presenza di una o più sostanze attive non esplicitamente menzionate in questo pannello informazionale, non implica che tali sostanze attive siano utilizzate in questo prodotto come sostanze attive attive.
Mental health problems while taking Calcort

Mental health problems can happen while taking steroids like Calcort (see also section 4 Possible Side Effects).

- 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, if problems do happen, they might continue for a while even after treatment.

Talk to a doctor if you (or someone taking this medicine), show any signs of mental problems. This is particularly important if you are depressed, or might be thinking about suicide.

In a few cases, mental problems have happened when doses are being lowered or stopped.

Check with your doctor before taking this medicine if:

- You have epilepsy (fits).
- You or anyone in your family has diabetes.
- You have high blood pressure.
- You have liver or heart problems.
- You have kidney problems or high levels of uric acid in your blood before initiating Calcort.

You should tell your doctor if you have any symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances, shortness of breath, seizures, irregular heartbeat or kidney failure (reduced amount or darkening of urine), in case you suffer from haematological malignancy (see section 4. Possible Side effects).

- You have had a previous severe allergic reaction to any of the ingredients in Calcort.
- You have had an anaphylactic shock.
- You have problems with your digestive system, including ulcer disease, peptic ulcer, ectopic ulcer (in the structure and function of the muscular stomach wall).
- You have ever had a bad reaction such as a stomach ulcer.
- You have ever had a bad reaction such as a stomach ulcer.
- You have muscle weakness to any steroid.
- You have ever had a stomach ulcer.
- You have a heart condition that could affect the eye.
- You have ever had a bad reaction such as a stomach ulcer.
- You have ever had diabetes.

You should tell your doctor if you have problems with your digestive system, including ulcer disease, peptic ulcer, ectopic ulcer (in the structure and function of the muscular stomach wall).

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- You have ever had diabetes.

Some medicines may increase the effects of Calcort and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV, retinovir, cobicistat).

- In particular, check with your doctor if you are taking any of the following medicines. Your doctor may want to change the dose of Calcort, or the other medicine:
  - Painkillers such as aspirin.
  - Aminoglutethimide - used for some types of cancer.
  - Ketocazole - used to treat fungal infections.
  - Water tablets (diuretics) such as spironolactone, triameterene or amiloride.
  - Medicines for thinning your blood (such as warfarin).
  - Medicines for diabetes.
  - Medicines for epilepsy such as phenobarbitalone, primidone, phenytoin, carbamazepine, acetazolamide.
  - Medicines which contain oestrogens including oral contraceptives.
  - Medicines for tuberculosis (TB) such as rifampicin or rifabutin.
  - Medicines for high blood pressure.
  - Medicines for indigestion and heartburn (antacids). If you are taking an antacid leave at least 2 hours between taking it and Calcort.
  - Medicines for asthma such as salbutamol and theophylline.

Vaccinations

If you have just had any injections or vaccinations, tell your doctor or pharmacist if you are taking Calcort. This includes those needed for a foreign holiday. Some vaccines should not be given to patients taking Calcort. This is because Calcort can affect the way some vaccines work.

Operations

If you are going to have an operation, tell your doctor or nurse if you are taking Calcort. Muscle relaxants are sometimes used during an operation or in intensive care unit. Calcort and muscle relaxants can affect one another.

Pregnancy and breast-feeding

- You have problems with your digestive system, including ulcer disease, peptic ulcer, ectopic ulcer (in the structure and function of the muscular stomach wall).
- You have ever had a bad reaction such as a stomach ulcer.
- You have muscle weakness to any steroid.
- You have ever had a stomach ulcer.
- You have a heart condition that could affect the eye.
- You have ever had a bad reaction such as a stomach ulcer.
- You have ever had diabetes.

You should tell your doctor if you are planning to become pregnant or If you are breastfeeding.

- You should not take Calcort during your first two months of pregnancy.
- You should take Calcort for no longer than four months during pregnancy.
- You should tell your doctor if you are planning to breast-feed.

Elderly

- You need to take Calcort regularly to get the medicine working.
- If you forget to take Calcort, you should take the missed dose as soon as you remember. If you are going to take a double dose make up for the forgotten dose.

Pregnancy and breast-feeding

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How Calcort works

• These corticosteroids occur naturally in the body, and help to maintain health and wellbeing.
• Boosting your body with extra corticosteroid (such as Calcort) is an effective way to treat various illnesses involving inflammation in the body.
• Calcort works by reducing this inflammation, which could otherwise go on making your condition worse.
• Calcort also works by stopping reactions known as autoimmune reactions. These reactions happen when your body’s immune system attacks the body itself and causes damage.
• You must take this medicine regularly to get maximum benefit from it.

2. Before you take Calcort

Do not take this medicine and tell your doctor if:

• You are allergic (hypersensitive) to deflazacort or any of the other ingredients in these tablets (see Section 6: Further information). Signs of an allergic reaction include: a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.
• You have an infection that affects your whole body (systemic infection), which is not already being treated.
• You are having or have recently had any vaccinations with live viruses (see “vaccinations” below).

Take special care and check with your doctor before you take Calcort if:

• You have ever had severe depression or manic-depression (bipolar disorder). This includes having had depression before while taking steroid medicines like Calcort.
• Any of your close family has had these illnesses.
• You have or ever had mental problems such as depression or psychoses.

If any of the above applies to you, talk to a doctor before taking Calcort.

3. How to take Calcort

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

4. Possible side effects

Important things you need to know about Calcort

Calcort is a steroid medicine. This can be 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 lower the dose gradually.
• Calcort can cause side effects in some people (read section 4 for more information). These include problems such as mood changes (feeling depressed, or ‘high’), or stomach problems, which can happen straight away. If you feel unwell in any way, keep taking your tablets, 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 rounded face (read section 4 for more information).
• If you take it for more than 3 weeks, you will be given 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, measles 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.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

Read all of this leaflet carefully before you start taking this medicine

• Keep this leaflet. You may need to read it again.
• If you have any further questions, please ask your doctor or pharmacist.
• This medicine has been prescribed for you. Do not give it to others. It may harm them, even if their symptoms are the same as yours.
• If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
• Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

In this leaflet:

1. What Calcort is and what it is used for
2. Before you take Calcort
3. How to take Calcort
4. Possible side effects
5. How to store Calcort
6. Further information

5. How to store Calcort

Keep this medicine below 25°C. Keep it in the pack it came in and out of the reach of children.

If you notice any of these problems talk to a doctor straight away.

Other side effects:

Please tell your doctor or pharmacist if any of the following side effects get serious or last longer than a few days.

Uncommon (affects 1 to 10 users in 1,000)

• Stomach or bowel problems such as feeling full or bloated, indigestion, heartburn or stomach pain.
• Increased thirst and needing to pass water more often than usual. These could be signs of diabetes. If you are already diabetic, your doctor may prescribe more of your diabetes medicine to balance the effects of deflazacort. You should discuss this with your doctor.
• Raised blood pressure and increased water retention.
• Tiredness, confusion, muscle weakness or muscle cramps. This may be due to low levels of potassium in your body.
• Mood changes, difficulty in sleeping.
• You have had tuberculosis (TB) in the past it may return.
• Skin problems such as acne, appearance of stretch marks.
• You may get infections more easily than usual.

Rare (affects 1 to 10 users in 10,000)

• Bleeding under the skin, redness.
• General muscle weakness or tiredness.

Not known (frequency cannot be estimated from the available data)

• Bones and tendons may break or tear more easily than usual. Also tendons may get inflamed and become painful.
• Irregular periods in women or they may stop altogether.
• Becoming dependent on deflazacort (also called psychological dependence).
• If you have schizophrenia your symptoms may get worse.
• Fungal infection such as thrush.
• Eye disease that causes detachment of the retina and bulging eyes.
• Eye problems such as glaucoma and cataracts can happen if you take this medicine for a long time.
• Eye infections (viral) may spread or return if you have had them in the past.

Blurred vision.
• Increase in the risk of cataracts forming in your blood.
• Blood problems such as leukaemia.
• Increased bruising and cuts do not heal as quickly as usual.
• Noticeable blood vessels, thinning of the skin.
• Sudden or severe muscle weakness or tiredness following an operation.

Some of the side effects are more likely to happen if you are elderly.

Children and teenagers taking this medicine may grow less than normal. (Not known: frequency cannot be estimated from the available data).

If you think this is happening to a child, tell your doctor.

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.

6. Further information

What Calcort contains

• Each tablet contains 6mg of the active substance, deflazacort.
• The other ingredients are microcrystalline cellulose, lactose, maize starch and magnesium stearate.

What Calcort looks like and contents of the pack

Calcort 6mg Tablets are round, white, uncoated tablets, marked with a cross on one face and a ‘6’ on the other face.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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