PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a physician's prescription only

Efmody 5 mg modified-release hard capsules
Efmody 10 mg modified-release hard capsules

The active ingredient and its quantity:

Each Efmody 5 mg modified-release hard capsule contains:

5 mg hydrocortisone

Each Efmody 10 mg modified-release hard capsule contains:

10 mg hydrocortisone

For a list of inactive and allergenic ingredients in the preparation, see section 6 "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, consult the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Efmody is intended for the treatment of congenital adrenal hyperplasia (CAH) in adolescents aged 12 years and over and adults.

Therapeutic group: Corticosteroids for systemic use - glucocorticoids. This medicine contains the active ingredient hydrocortisone. Hydrocortisone belongs to a group of medicines known as corticosteroids.

Hydrocortisone is a copy of the hormone cortisol. Cortisol is made by the adrenal glands in the body. Efmody is indicated in conditions where the adrenal glands do not produce enough cortisol due to a hereditary condition called congenital adrenal hyperplasia. It is intended for use in adults and adolescents aged 12 years and over.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient hydrocortisone or to any of the additional ingredients that the medicine contains (see section 6 - "Further information").

Special warnings regarding use of the medicine

Before treatment with Efmody, tell the doctor if any of the following conditions applies to you:

- Adrenal crisis

If you have an adrenal crisis. If you are vomiting or feeling seriously unwell, you may need an injection of hydrocortisone. Your doctor will instruct you how to do this in an emergency.

- Infections

If you have an infection or you do not feel well. Your doctor may need to prescribe an increased dose of hydrocortisone temporarily.

- Immunisation

If you are going to be vaccinated. Usually, taking Efmody should not prevent you from receiving a vaccination.

- Fertility

If you have had reduced fertility due to congenital adrenal hyperplasia, your fertility may be restored, sometimes soon after starting treatment with Efmody. This applies to both men and women. Consult with your doctor about methods of contraception before starting treatment with Efmody.

- Other

- You are going to have an operation. Before your operation, tell the surgeon or anesthetist that you are taking Efmody.
- You have been suffering for a long time from a disorder of your digestive system (such as chronic diarrhea) that affects how well your gut absorbs food. Your doctor may prescribe another medicine instead of this one or monitor your condition more closely to check that you are receiving the right amount of the medicine.
  - Do not stop taking Efmody without checking with your doctor as this could make you feel seriously unwell within a short time.
- As Efmody is replacing a natural hormone that your body lacks, side effects are less likely; however:
  - Too much Efmody can affect your bones. Your doctor will therefore monitor the treatment.
  - Some patients taking hydrocortisone/Efmody have suffered from anxiety, depression or confusion. Tell your doctor if you develop any unusual behaviour or if you have suicidal thoughts after starting treatment with this medicine (see section 4).
  - In rare instances, allergy to hydrocortisone can occur. People who already have allergies to other medicines may be more likely to develop an allergy to hydrocortisone. Tell your doctor immediately if you have any reaction such as swelling or shortness of breath after taking Efmody (see section 4).
  - Hydrocortisone may cause diabetes. If you have symptoms of excessive thirst or increased need to urinate, tell your doctor immediately.
  - Contact your doctor if you have blurred vision or other visual disturbances.

Children and adolescents:

- Efmody is not intended for use by children under the age of 12 years. There is no information about the safety and efficacy of this preparation in children under the age of 12 years.
- Hydrocortisone can cause growth delay in children. Your doctor will monitor your growth while you are taking Efmody.
- Some children with congenital adrenal hyperplasia who take hydrocortisone can show signs of sexual development or maturity earlier than expected. Your doctor will monitor your development while you are taking Efmody.

Tests and follow-up

- Treatment with steroids can lead to low blood potassium. Your doctor will monitor your potassium levels to check for any changes.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Some medicines can affect the way that Efmody works, which means that your doctor may need to change your dose of Efmody.

Your doctor may need to increase your dose of Efmody, particularly if you take other medicines, including liver enzyme inducers, such as:

- Medicines used to treat epilepsy: phenytoin, carbamazepine, oxcarbazepine and barbiturates such as phenobarbital and primidone.
- Medicines used to treat infections (antibiotics): rifampicin and rifabutin.
- Medicines used to treat human immunodeficiency virus (HIV) infection and AIDS: efavirenz and nevirapine.
- Herbal medicines used to treat depression, e.g. St. John's wort.

Your doctor may need to decrease your dose of Efmody, particularly if you take other medicines, including liver enzyme inhibitors such as:

- Medicines used to treat fungal diseases: itraconazole, posaconazole and voriconazole.
- Medicines used to treat infections (antibiotics): erythromycin and clarithromycin.
- A medicine used to treat human immunodeficiency virus (HIV) infection and AIDS: ritonavir.

Use of the medicine and food

Some foods and beverages may affect the way Efmody works and may require your doctor to decrease your dose. These include:

- Grapefruit juice.
- Licorice.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult with the doctor before taking this medicine. Hydrocortisone is known to cross the placenta during pregnancy and is present in breast milk; however, there is no evidence that this causes any harm to the infant.

If you are a woman who has not gone through menopause, your periods may return or become more regular. The restored fertility may lead to unexpected pregnancy even before the recurrence of menstrual bleeding. See also section "Special warnings regarding use of the medicine" regarding fertility in both men and women.

Driving and operating machinery

Efmody has a negligible effect on the ability to drive and use machines. Untreated adrenal insufficiency may affect the ability to drive and use machines. Inform your doctor immediately if you feel tired or dizzy when taking Efmody.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation in accordance with the doctor's instructions.

You should check with the doctor or pharmacist if you are unsure about the dosage or treatment regimen for the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally:

The initial daily dose may be divided into 2 doses, with two thirds to three quarters of your daily dose in the evening at bedtime, and the rest in the morning.

The morning dose of hydrocortisone modified-release hard capsules should be taken on an empty stomach at least 1 hour before a meal. The evening dose should be taken at bedtime at least 2 hours after the last meal of the day.

During illnesses, in case of surgery and during times of extreme stress, your doctor may ask you to take another corticosteroid medicine instead of, or as well as, Efmody.

Do not exceed the recommended dose

If you feel unwell

Tell your doctor or pharmacist if you feel unwell, are suffering from severe stress, suffer an injury or are about to have surgery, because your doctor may advise that you take another corticosteroid medicine instead of, or as well as, Efmody (see section 2).

Crushing/splitting/chewing:

Swallow the capsules with water.

Do not chew the capsules, as this could modify how the medicine is released.

Discontinuing the medicine

Do not stop taking Efmody without first speaking with your doctor. Stopping the medicine suddenly can quickly lead to an adrenal crisis.

If you accidentally took a higher dose or if a child has accidentally swallowed the medicine, immediately consult a doctor or proceed to a hospital emergency room and bring the package of medicine with you.

If you forgot to take this medicine at the scheduled time, take the next dose as soon as possible and consult the doctor. **Do not take a double dose.** Adhere to the treatment regimen as recommended by the doctor.

Do not take medicines in the dark! Check the label and dose every time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

As with any medicine, the use of Efmody may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

- If you have any reaction, such as swelling or shortness of breath, after taking Efmody, get medical help right away and inform your doctor as soon as possible, as these can be signs of a severe allergic reaction (anaphylactoid reactions) (see section 2).
- Adrenal crisis and adrenal insufficiency symptoms have been reported often (may occur in up to 1 in 10 people). If you receive less hydrocortisone than you need, you may feel very unwell. If you feel unwell, particularly if you start vomiting, you must inform your doctor right away, as you may need a higher dose of hydrocortisone or an injection of hydrocortisone.

Consult a doctor immediately if you have any of the following side effects:

Very common side effects (may occur in more than 1 in 10 people)

- Tiredness

Common side effects (may occur in up to 1 in 10 people)

- Nausea
- Abdominal pain
- Loss of energy or weakness
- Increased or decreased appetite and weight gain or loss
- Muscle pain and weakness
- Joint pain
- Headache
- Dizziness
- Pain or tingling in the thumb or fingers (carpal tunnel syndrome)
- Tingling
- Insomnia, sleep difficulties or unusual dreams
- Depressed mood
- Acne
- Hair growth
- Changes in blood tests for kidney function and glucose

Long-term treatment with hydrocortisone may cause reduced bone density. Your doctor will monitor your bone status (see section 2).

People who require treatment with steroids may have a higher risk of heart disease. Your doctor will monitor you for this.

Long-term treatment with hydrocortisone can affect growth in children and young people. The doctor will monitor growth in young people. Some children with congenital adrenal hyperplasia treated with hydrocortisone may reach puberty earlier than expected. The doctor will monitor development (see section 2).

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects Due to Drug Treatment" on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp.date) that appears on the package/bottle. The expiry date refers to the last day of that month.

Storage conditions:

There are no special storage requirements for this medicine. It is recommended to store it at room temperature.

Store in the original package.

Keep the bottle tightly closed in order to protect from moisture.

Do not throw away the medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. This will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

microcrystalline cellulose, povidone, methacrylic acid-methyl methacrylate copolymer, talc, dibutyl sebacate.

- The capsule is made from gelatin.

Efmody 5 mg modified-release hard capsules (white/blue)

titanium dioxide (E171), indigotine (E132)

Efmody 10 mg modified-release hard capsules (white/green)

titanium dioxide (E171), indigotine (E132), yellow iron oxide (E172)

Printing ink

The printing ink on the capsules contains:

shellac, black iron oxide (E172), propylene glycol, potassium hydroxide

What the medicine looks like and what the package contains:

- Efmody 5 mg modified-release hard capsules

  A capsule (approx. 19 mm long) with an opaque blue cap and opaque white body, printed with "CHC 5mg", containing white to off white granules.
- Efmody 10 mg modified-release hard capsules

  A capsule (approx. 19 mm long) with an opaque green cap and opaque white body, printed with "CHC 10mg", containing white to off white granules.

Efmody comes in high density polyethylene bottles with child resistant, tamper-evident polypropylene screw cap with integrated desiccant.
Each bottle contains 50 modified-release hard capsules.

Package size:

Package containing one bottle of 50 modified-release hard capsules.

Package containing 2 bottles of 50 modified-release hard capsules (100 capsules).

Not all package sizes may be marketed.

Registration holder and address

Medomie Pharma Ltd., 5358305, POB 816, Giv'atayim.

Manufacturer

Diurnal Europe B.V.
Van Heuven Goedhartlaan 935 A,
1181LD Amstelveen,
The Netherlands

Importer

Medison Pharma Ltd.,

POB 7090 Petach Tikva

Revised in September 2023 according to Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Efmody 5 mg 173-54-37410-99
Efmody 10 mg 173-55-37411-99