

# Hydrocortisone Roussel® 10 mg

scored tablets

*hydrocortisone*

## 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 questions or are unsure of anything, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you personally and you should 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 doctor or pharmacist.

## In this package leaflet:

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### 1. WHAT Hydrocortisone Roussel 10 mg scored tablets ARE AND WHAT THEY ARE TAKEN FOR

#### GLUCOCORTICOIDS – SYSTEMIC USE

(H: systemic hormonal preparations, excl. sex hormones)

This medicine is prescribed as replacement treatment for patients with adrenal failure (i.e. if secretion of hormones by your adrenal glands has been reduced or stopped).

### 2. BEFORE YOU TAKE Hydrocortisone Roussel 10 mg scored tablets

If your doctor has told you that you have an intolerance to certain sugars, contact him/her before taking this medicine.

IF YOU ARE UNSURE OF ANYTHING, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

## Take special care with Hydrocortisone Roussel 10 mg scored tablets:

### Special warnings

It is important that your diet includes a normal amount of salt if you have adrenal failure.

Oral or injectable corticosteroids can increase the risk of tendinitis, or even tendon rupture in exceptional cases. Tell your doctor if you have tendon pain.

Taking this medicine with sultopride (a medicine that acts on the central nervous system) or live attenuated vaccines must be avoided (see Taking/using other medicines).

Use of this medicine is not recommended if you have galactose intolerance, are lactase-deficient or have glucose malabsorption syndrome or (rare hereditary diseases).

### Precautions for use

Never stop treatment without first consulting your doctor.

Tell your doctor without delay if your body has been affected by any unusual stressful situation (fever, infection, illness, surgery, injury) as hydrocortisone doses may need to be increased.

IF YOU ARE UNSURE OF ANYTHING, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

### Taking/using other medicines

Taking this medicine with sultopride (a medicine that acts on the central nervous system) or live attenuated vaccines must be avoided (see Special warnings).

If you are taking or have recently taken another medicine, including an over-the-counter medicine, inform your doctor or pharmacist.

### Pregnancy and breast-feeding

If necessary, your doctor may need to prescribe this medicine during pregnancy or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

### Athletes

You should be aware that this medicine contains hydrocortisone, which is on the list of doping substances.

**List of excipients with a specific effect:** lactose.

### 3. HOW TO TAKE Hydrocortisone Roussel 10 mg scored tablets

#### How many Hydrocortisone Roussel 10 mg scored tablets should be taken

Dosage and treatment duration vary depending on the condition being treated.

In all cases, strictly follow your doctor's prescription: comply with prescribed doses, dose times, and treatment duration.

Never stop treatment without consulting your doctor (see [Precautions for use](#)).

#### How to take Hydrocortisone Roussel 10 mg scored tablets

Oral route.

Swallow the tablets with a glass of water.

For children aged under 6, tablets can be cut depending on the dose, then crushed and mixed with food.

#### When and how often Hydrocortisone Roussel 10 mg scored tablets should be taken

This medicine must be taken during meals.

#### How long Hydrocortisone Roussel 10 mg scored tablets should be taken

Follow your doctor's prescription.

#### If you take more Hydrocortisone Roussel 10 mg scored tablets than you should

The risks are minor considering what the medicine is taken for. However, if you do take too much of this drug, consult your doctor immediately.

#### If you forget to take Hydrocortisone Roussel 10 mg scored tablets

Never take several doses at once. If treatment is interrupted, contact your doctor.

### 4. POSSIBLE SIDE EFFECTS

As with all medicines, **Hydrocortisone Roussel 10 mg scored tablets** can cause side effects, although not all patients have them.

A few exceptional cases of tendon rupture have been reported, particularly when the drug is administered in combination with fluoroquinolones.

If you notice any side effects not mentioned in this leaflet, or if certain side effects become serious, please inform your doctor or pharmacist.

### 5. HOW TO STORE Hydrocortisone Roussel 10 mg scored tablets

Keep out of the reach and sight of children.

Do not use **Hydrocortisone Roussel 10 mg scored tablets** after the expiry date printed on the box.

Store at a temperature no higher than 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of unused medicines. These measures will help to protect the environment.

### 6. FURTHER INFORMATION

#### What do Hydrocortisone Roussel 10 mg scored tablets contain?

##### The active substance is:

Hydrocortisone ..... 10.00 mg  
for one scored tablet.

##### The other ingredients are:

Pregelatinized maize starch, lactose monohydrate, magnesium stearate, talc.

#### How Hydrocortisone Roussel 10 mg scored tablets are supplied and contents of the outer packaging

This medicine is available as scored tablets.

Box of 25 tablets.

Some presentations of the drug may not be commercialized.

#### Marketing Authorization Holder and Operating Company

##### sanofi-aventis France

1-13, boulevard Romain Rolland  
75014 Paris  
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##### Manufacturer

SANOFI WINTHROP INDUSTRIE  
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