

HYDROCORTISONE MEDIS® 100 mg

Freeze dried powder for parenteral use I.M-I.V

DCI : Hydrocortisone sodium succinate

Please read carefully the integrality of this notice before taking this drug.

- Keep this notice; you may need to read it again.
- If you have further questions, if you have any doubt, ask your doctor or pharmacist for more information.
- This drug was prescribed for you personally. Never give it to someone else, even in case of identical symptoms; this could be harmful for this person.
- If one of the undesirable effects worsens or if you experience an undesirable effect which is not mentioned in this notice, inform your doctor or your pharmacist.

In this notice:

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1. What HYDROCORTISONE MEDIS 100 mg is and what it is used for
HYDROCORTISONE MEDIS 100 mg is a drug composed by an active substance, the Sodium Hydrocortisone succinate. This specialty belongs to the pharmaco-therapeutic class: Glucocorticoid Hormone
This drug is indicated in the treatment of adrenal insufficiency (diminution or absence of secretion of the hormones secreted by the adrenal glands), transient adrenal insufficiency of the newborn, congenital Hyperplasia of the adrenal glands with salt loss syndrome (syndrome of Debré-Fibiger)

2. Before you take HYDROCORTISONE MEDIS 100 mg
Do not take HYDROCORTISONE MEDIS 100 mg
If you are allergic (hypersensitive) to the sodium hydrocortisone succinate or to one of the components of HYDROCORTISONE MEDIS 100 mg.
In case of doubt, it is necessary to ask your doctor or pharmacist advice.

Take special care with HYDROCORTISONE MEDIS 100 mg
Diet: it is imperative to continue a normal salt diet in the case of adrenal insufficiency.

The oral or injectable corticoids can favor the occurrence of tendinopathies, and even tendon rupture (exceptional). Prevent your doctor in case of appearance of tendon pains.

Rapidly inform your doctor about any aggression factor (fever, infection, disease, surgical intervention, traumatism), because this may require a dose increase.

In case of doubt, it is necessary to ask your doctor or pharmacist advice.

Taking HYDROCORTISONE MEDIS 100 mg with other medicines
If you take or you have recently taken other drugs, even those obtained without medical prescription, inform your doctor or your pharmacist.

Taking HYDROCORTISONE MEDIS 100 mg with Food and drinks
Without subject.

Pregnancy and breastfeeding
When needed, this drug can be taken during pregnancy.
This drug should be avoided during breastfeeding.
Ask your doctor or your pharmacist advice before taking any drug.

Sportmen and sportswomen
Sportmen and sportswomen: be careful: this specialty contains an active substance susceptible to induce a positive reaction in the doping control tests

Driving and using machines
Without subject.

Important information concerning some components of HYDROCORTISONE MEDIS 100 mg
Without subject.

3. How to use HYDROCORTISONE MEDIS 100 mg
Always respect the dosage of HYDROCORTISONE MEDIS 100 mg indicated by your doctor. In case of doubt, it is necessary to ask your doctor or pharmacist advice.

The usual dose is:
The dosage and the treatment duration depend on the affection to be treated.

Mode of administration
Intravenous route, Intramuscular route, possible.
The freeze-dried in the vial must be dissolved by the addition of contents of the

ampoule of solvent. If necessary, we can further dilute the obtaining solution through a sterile isotonic solute.
The prepared solutions should be used within a maximum of 24 hours.
This specialty is to be administered by intravenous route in local injection or in infusion.
This solution can be administered by intramuscular route at the same dose.

Frequency of administration
Conform yourself to your doctor prescription.

Treatment duration
The duration is determined by the prescribing doctor.

If you used more HYDROCORTISONE MEDIS 100 mg than you should
If you used more HYDROCORTISONE MEDIS 100 mg than you should, contact your doctor or your pharmacist since it is possible.

If you forgot to use HYDROCORTISONE MEDIS 100 mg
Don't take a double dose to compensate the forgotten dose.

If you discontinue HYDROCORTISONE MEDIS 100 mg
Ask your doctor advice before discontinuing the use of HYDROCORTISONE MEDIS 100 mg.

If you have any other questions about the use of this drug, ask your doctor or your pharmacist for more information.

4. Possible side effects
Like all the other drugs, HYDROCORTISONE MEDIS 100 mg can provoke undesirable effects. However, all the patients will not experience these effects.
- Some cases of tendons ruptures were exceptionally reported, especially in case of concomitant prescription of Fluoroquinolones.
- Rare cases of general allergic reactions.

If you think that one of the above mentioned effects as being severe or if you present undesirable effects which are not mentioned in this notice, please inform your doctor or your pharmacist

5. How to store HYDROCORTISONE MEDIS 100 mg
Store away light in packing external of origin.
Keep out the reach and sight of children.

6. Further Information
What are the components of HYDROCORTISONE MEDIS 100 mg composition per vial?

Active ingredient :	
Hydrocortisone sodium succinate 133.67 mg (100 mg as base)
Excipients :	
Sodium Hydroxyde - s.q.

What is HYDROCORTISONE MEDIS 100 mg and external packaging content?

Specialities	Presentations	M.A. numbers
HYDROCORTISONE MEDIS 100 mg	Box of 01 vial of lyophilized powder + 1 ampoule of solvent of 2 ml	923 359 3
HYDROCORTISONE MEDIS 100 mg	Box of 10 vials of lyophilized powder	923 359 1H

Marketing authorization holder and manufacturer

Marketing authorization holder:
Les Laboratoires des Médicaments Stériles - S.A
Route de Nabeul - KM 7 - BP 206 8000 Nabeul - Tunisie
Tel : (216) 72 23 50 06
Fax: (216) 72 23 51 06

Manufacturer:
Les Laboratoires des Médicaments Stériles - S.A.
Route de Nabeul - KM 7 - BP 206 8000 Nabeul - Tunisie
Tel: (216) 72 23 50 06
Fax: (216) 72 23 51 06

DATE OF THE LAST REVISION OF THIS LEAFLET : October 2012

This is a drug

- A drug is a product but it is different from the other products.
- A drug is a product which acts on your health and its non appropriate consumption can expose you to danger.
- Rigorously respect your doctor's prescription and the mode of administration he prescribed. Follow your pharmacist's advices.
- Your doctor and your pharmacist know drugs, their indications and contra-indications.
- Do not stop on your own initiative the treatment during the prescribed period
- Do not retake, do not increase doses without consulting your doctor.

KEEP ANY DRUG OUT OF THE REACH OF CHILDREN.



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