

# Drug Information Sheet("Kusuri-no-Shiori")

Self-injection  
Revised: 08/2021

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

**Brand name:**Solu-Cortef Injection 100mg [self-injection for acute adrenocortical insufficiency]

**Active ingredient:**Hydrocortisone sodium succinate

**Dosage form:**injection (white powder or mass with attached solution)

**Print on wrapping:**



## Effects of this medicine

This medicine has a similar action to adrenocortical hormone which is produced in the body and supplies adrenocortical hormone lacking in the body.

It is usually used to treat acute adrenocortical insufficiency (adrenal crisis).

## Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itching, rash, etc.) to any medicines.  
If you have infection or a joint with abnormal mobility.  
If you have infection with no effective antibacterial agents, generalized mycosis, peptic ulcer, diverticulitis, psychosis, tuberculosis disease, herpes simplex keratitis, posterior subcapsular cataract, glaucoma, hypertension, abnormal electrolyte or thrombosis.  
If you have had a surgery in visceral organ recently.  
If you have a history of acute myocardial infarction.  
If you have viral conjunctival/corneal disease, tuberculous eye disease, fungal eye disease or acute suppurative eye disease.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

## Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is(( to be written by a healthcare professional))
- In general, this medicine is injected intramuscularly once. Strictly follow the instructions.
- Use this medicine only when you have a symptom. Ask the doctor about how to use.
- Use this medicine as soon as possible after the powder is dissolved in the solution.
- If any of the following symptoms suggestive of acute adrenocortical insufficiency (adrenal crisis) occur, you or your family should promptly inject this medicine intramuscularly: general symptoms (you cannot take medicines usually administered/are severely limp), digestive symptoms (you vomit repeatedly/have severe abdominal pain), nervous symptoms (you are semi-conscious/experience convulsion) or cardiovascular symptoms (your pulse is weak or difficult to palpate/blood pressure is extremely lower than usual). The dose for one injection at the onset of acute adrenocortical insufficiency (adrenal crisis) is different according to the age/body weight. Ask your doctor about the dose for an emergency in advance. As well, receive medical examination at a medical institution immediately after the self-injection.
- If your doctor consider you are at high risk for acute adrenocortical insufficiency (adrenal crisis) and you or your family receive appropriate instructions at a medical institution for self-injection at home, you or your family may self-inject this medicine for acute care of acute adrenocortical insufficiency (adrenal crisis). Receive an explanation to fully understand how to prepare and intramuscularly inject this medicine and how to discard the devices and strictly follow the instructions.
- If you accidentally inject more than your prescribed dose, consult with your doctor or pharmacist.

## Precautions while taking this medicine

- Avoid stress such as extreme exercise because serious adverse reaction such as induced infections may occur. Also pay attention not to catch chickenpox or measles.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea/vomiting, moon face, itching, rash, erythema and instability of the joint (when intraarticularly injected). If any of these symptoms occur, consult with your doctor or pharmacist.

**The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.**

- fever, general malaise, cough [infection]

- general malaise, loss of appetite, nausea [secondary adrenocortical insufficiency]
- pain in the lower back/back/chest/groin, pain in the hip joint when walking or standing up, fracture [osteoporosis, aseptic necrosis of bone head]
- severe abdominal pain, bloody stool, heartburn [gastrointestinal perforation, gastrointestinal bleeding, peptic ulcer]
- delusion, euphoria, depressed mood and decreased motivation [mental abnormality, depressive state]

**The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.**

**Storage conditions and other information**

- Keep out of reach of children. Store at room temperature (1 to 30 degrees Celsius) away from direct sunlight and moisture.
- Once this medicine is taken out of the outer carton, store away from light.
- Discard the remainder. Do not store them.
- Be sure to consult with your doctor, when receiving a live vaccine or live attenuated vaccine.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.