

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

External

Revised: 02/2022

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: Polymyxin B Sulfate Powder 0.5MU Pfizer [Topical administration]

Active ingredient: Polymixin B sulfate

Dosage form: white to yellowish brown powder

Print on wrapping:

バイアルに入っています

Effects of this medicine

This medicine is polypeptide antibiotic that has bactericidal effect by changing the permeability of the cytoplasmic membrane of bacteria that causes disease (infection).

It is usually used to treat secondary infection of injury/burn and surgical wound, osteomyelitis, arthritis and cystitis. Not effective against fungal or virus infection.

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: renal disorder, an ear surgery recently or perforation of tympanum (if you use for the ear).
- 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))
- For treatment of secondary infection of injury/burn and surgical wound: In general, for adults, dissolve 1 vial (0.5 MU of the active ingredient) to 5 to 50 mL distilled water for injection or saline, and spray appropriate amount of medicine to the affected area. The maximum single dose is up to 1 vial (0.5 MU).
For treatment of osteomyelitis, arthritis, otitis media or sinusitis: In general, for adults, dissolve 1 vial (0.5 MU of the active ingredient) to 10 to 50 mL distilled water for injection or saline, and inject or spray appropriate amount of medicine to the affected area. The maximum single dose is up to 1 vial (0.5 MU).
For treatment of cystitis: In general, for adults, dissolve 1 vial (0.5 MU of the active ingredient) to 10 to 500 mL sterile purified water or saline, and wash out or inject appropriate amount of medicine into the bladder in 1 to 2 divided doses per day. The maximum single dose is up to 1 vial (0.5 MU).
For treatment of conjunctivitis or keratitis (including corneal ulcer): In general, for adults, dissolve 1 vial (0.5 MU of the active ingredient) to 20 to 50 mL distilled water for injection or saline, and instill appropriate amount of medicine into the eye.
In any case, strictly follow the instructions.
- If you miss a dose, use the missed dose as soon as possible. You should never use two doses at one time.
- If you accidentally use more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop using this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include renal disorder, sensory abnormality, dizziness, headache, fever, sleepiness, ataxia, vision disorder, rash and itching. 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.

- facial pallor, cold sweat, loss of consciousness [shock]
- hard to hear voices and sounds, breathing difficulty [impaired hearing, respiratory depression by neuromuscular blocking action]

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 away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.