

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

Injection

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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:** TEPEZZA for Intravenous Infusion 500mg

**Active ingredient:** Teprotumumab (genetical recombination)

**Dosage form:** injection

**Imprint or print on wrapping:**



## Effects of this medicine

This medicine improves fibrosis of the tissues around eyes by binding to insulin-like growth factor-1 receptor (IGF-1R) and suppressing its activation and signaling pathway.

It is usually used to treat active thyroid ophthalmopathy.

## The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
- If you have hearing impairment.
- If you have diabetes mellitus or glucose tolerance disorder.
- If you have inflammatory bowel disease.
- If you are pregnant, possibly 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, inject this medicine with intravenous drip infusion for 8 times once every 3 weeks.

## Precautions while taking this medicine

- If you are a female patient with a possibility of pregnancy, avoid pregnancy while using this medicine and for 5 months after the completion of the medication.
- Audibility test should be performed periodically. Take the test under the instruction of your doctor.
- Blood glucose level recommended to be measured periodically. Take the test under the instruction of your doctor.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include tinnitus, hair loss and diarrhea. 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.**

- decreased hearing, tinnitus, ear stuffiness [hearing impairment]
- body dullness, decreased body weight, dry mouth [hyperglycemia]
- fever, decreased consciousness, breathing difficulty, itching, rash [infusion reaction]

**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

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.