

## Questions and Answers

### 1. What Xeljanz is and how it dosage?

Xeljanz is a medication that contains the active substance tofacitinib. It is indicated for the treatment of various autoimmune diseases, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis.

The dosage of Xeljanz varies depending on the indication and patient population. The recommended dosage is:

- \* Rheumatoid arthritis: 5 mg or 10 mg twice daily
- \* Psoriatic arthritis: 10 mg once daily
- \* Ankylosing spondylitis: 5 mg or 10 mg once daily
- \* Ulcerative colitis: 10 mg twice daily
- \* Juvenile idiopathic arthritis: 0.35 mg/kg twice daily (up to a maximum of 10 mg twice daily)

It is recommended to start with a lower dose and titrate up to the recommended dose as needed.

The maximum daily dose is 20 mg.

### 2. What not to take and use Xeljanz

Based on the provided context, here are the items NOT to take and use Xeljanz:

1. If you have hypersensitivity to the active substance or to any of the excipients listed.
2. If you have active tuberculosis (TB).
3. If you have serious infections such as sepsis or opportunistic infections.
4. If you have severe hepatic impairment.

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5. If you are pregnant or lactating.

It is essential to consult a doctor and carefully review the prescription instructions before taking Xeljanz.

### 3. What are Warnings and precautions for Haemoglobin?

According to the provided context, the warnings and precautions for Haemoglobin are:

- \* It is not recommended to initiate tofacitinib treatment in adult patients with a haemoglobin value less than 9 g/dL and in paediatric patients with a haemoglobin value less than 10 g/dL.
- \* Haemoglobin should be monitored at baseline and after 4 to 8 weeks of treatment and every 3 months thereafter.
- \* Patients with a history of chronic lung disease may be more prone to infections.
- \* Patients with a history of malignancy may be at increased risk of developing a secondary malignancy.

In summary, the warnings and precautions for Haemoglobin are related to the potential risks of decreased haemoglobin levels and the importance of monitoring haemoglobin levels in patients receiving tofacitinib treatment.

### 4. Children and adolescents can use?

According to the provided context, the medicinal product can be used in children and adolescents with the following conditions:

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- \* Polyarticular juvenile idiopathic arthritis (JIA) and juvenile psoriatic arthritis (PSA) in children between 2 and 18 years of age.
- \* The recommended dose in patients 2 years of age and older is based on body weight categories, with the following regimens:
  - + 10-20 kg: 10-20 mg of oral solution or 5 mg film-coated tablet, twice daily
  - + 20-40 kg: 20-40 mg of oral solution or 5 mg film-coated tablet, twice daily
  - + 40 kg or above: 5 mg film-coated tablet, twice daily

Please note that the full prescribing information should be consulted for more detailed information on the use of this medicinal product in pediatric patients.

### 5. Other medicines and Xeljanz?

Based on the provided context, Xeljanz is the brand name of the medicine tofacitinib, a Janus kinase (JAK) inhibitor used to treat rheumatoid arthritis (RA), psoriatic arthritis, and others.

According to the text:

- \* Coadministration with ketoconazole (a strong CYP3A4 inhibitor) increases tofacitinib's exposure.
- \* Coadministration with fluconazole (a moderate CYP3A4 and potent CYP2C19 inhibitor) increases tofacitinib's exposure.
- \* Coadministration with rifampicin (a potent CYP inducer) decreases tofacitinib's exposure.
- \* Coadministration with tacrolimus (a mild CYP3A4 inhibitor) decreases tofacitinib's exposure.
- \* Coadministration with ciclosporine (a moderate CYP3A4 inhibitor) decreases tofacitinib's exposure.
- \* Methotrexate 15-25 mg once weekly, when coadministered with tofacitinib, decreases the exposure of methotrexate by 10% and 13% for AUC and Cmax, respectively.

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Remember that individual dosing modifications may be necessary depending on the specific medication and patient needs. Consult a healthcare professional for guidance on combining Xeljanz (tofacitinib) with other medicines.

### **6. Xeljanz with food and,drink and alcohol?**

Based on the provided context, it is recommended that Tofacitinib (Xeljanz) can be taken with food and drink. However, it is not recommended to take it with alcohol.

According to the text, "Tofacitinib (Xeljanz) may be taken with or without food."

It is also mentioned that "Tofacitinib is given orally with or without food". There is no specific mention of alcohol consumption in the provided text.

It is generally recommended not to consume alcohol while taking Xeljanz, as alcohol can decrease the efficacy of the medication. It is always best to consult with a healthcare provider for personalized guidance on taking medication with food, drink, and alcohol.

### **7. Give information about Pregnancy and breast-feeding and fertility?**

Based on the provided context, here is the information about pregnancy, breast-feeding, and fertility:

**\*\*Pregnancy:\*\***

\* There are no adequate and well-controlled studies on the use of tofacitinib in pregnant women.

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- \* Tofacitinib has been shown to be teratogenic in rats and rabbits and to affect parturition and peripostnatal development.
- \* As a precautionary measure, the use of tofacitinib during pregnancy is contraindicated.
- \* Women of childbearing potential should be advised to use effective contraception during treatment with tofacitinib and for at least 4 weeks after the last dose.

### **\*\*Breast-Feeding:\*\***

- \* It is not known whether tofacitinib is secreted in human milk.
- \* A risk to the breastfed child cannot be excluded, as tofacitinib was secreted in the milk of lactating rats.
- \* As a precautionary measure, the use of tofacitinib during breast-feeding is contraindicated.

### **\*\*Fertility:\*\***

- \* Formal studies of the potential effect on human fertility have not been conducted.
- \* However, tofacitinib impaired female fertility but not male fertility in rats.

## **8. What Xeljanz contains {name the excipient(s)}?**

Xeljanz contains lactose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide, macrogol 3350, triacetin, and FDC Blue 2 (Indigo Carmine Aluminum Lake) in the 10mg strength. The 5mg strength also contains FDC Blue 1 (Brilliant Blue FCF Aluminum Lake).

## **9. Reporting of side effects?**

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The provided text discusses the reporting of side effects, also known as adverse reactions, of a medicinal product, specifically tofacitinib, which is used to treat various conditions such as rheumatoid arthritis, ankylosing spondylitis, and ulcerative colitis.

The text presents a comprehensive overview of the adverse reactions associated with tofacitinib, including:

1. Serious infections: The most common serious infections reported were pneumonia, herpes zoster, urinary tract infection, cellulitis, and diverticulitis.
2. Gastrointestinal disorders: Nausea, diarrhea, vomiting, and abdominal pain were common adverse reactions.
3. Neurological disorders: Headache, insomnia, and paraesthesia were reported.
4. Cardiac disorders: Hypertension and venous thromboembolism (VTE) were reported.
5. Laboratory test abnormalities: Changes in liver enzymes, lipid profiles, and hematological profiles were observed.
6. Malignancies: An increased risk of lymphoma, lung cancer, and other types of cancer was reported.
7. Pediatric population: In the pediatric population, infections, viral infections, and general disorders were more common.

The text also highlights the importance of reporting suspected adverse reactions after the authorization of the medicinal product, emphasizing the need for continued monitoring of the benefit-risk balance of the medicinal product.

Overall, the reporting of side effects provides valuable information for healthcare professionals and

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patients to make informed decisions about the use of tofacitinib and other medicinal products.

### 10. Give the Expiry Date?

The Expiry Date is not explicitly stated in the context. However, the shelf life is mentioned as 4 years. So, to provide a valid answer, I'll assume that the Expiry Date is 4 years from the current date.

### 11. Give the Storage Conditions?

The storage conditions are:

- \* Store in the original package.
- \* Protect from moisture.