

Important information for you and your family when starting treatment with Xeplion TRI®

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This pamphlet introduces the schizophrenia medicine Xeplion TRI®. We believe you pursue recovery (self-realization). As you pursue recovery (self-realization), we hope that this pamphlet is useful for communication between you and the people who support you, such as family, peers, and healthcare professionals.

About Xeplion TRI®



Dosing interval

Xeplion TRI®* is produced based on Xeplion® (4-weekly release intramuscular injection). The efficacy of Xeplion TRI® has been extended to 12 weeks. You will receive treatment with Xeplion TRI® once every 12 weeks.

* TRI is an abbreviation of Twelve-Week Release Injection.



If your dosing interval can be extended to 12 weeks, ...

You receive injections less often.



You can use more time for psychological treatment, etc.

However, it may take longer to address any side effect that might occur. Also, your time between visits may become longer, so you should consult with your doctor or healthcare professional to determine the frequency of visits and means of communication (e.g., telephone, e-mail) that are best for you.

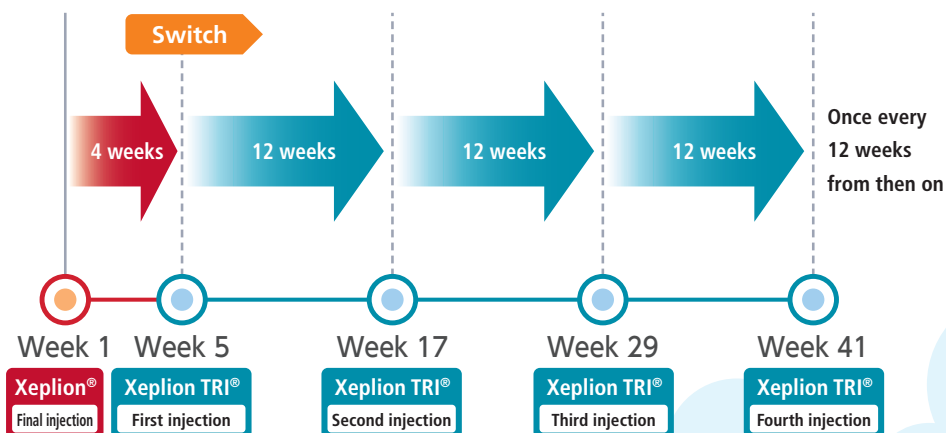




Dosing schedule

The first injection of Xeplion TRI[®] is given 4 weeks after the final injection of Xeplion[®] (4-weekly release intramuscular injection). After that, you will receive a Xeplion TRI[®] injection once every 12 weeks.

Xeplion TRI[®] can be injected into either the buttock muscle (gluteal muscle) or the shoulder muscle (deltoid muscle).



* The patient must have been on Xeplion[®] (4-weekly release intramuscular injection) for at least 4 months without concomitant use of another antipsychotics.



Precautions before starting Xeplion TRI®



You cannot use Xeplion TRI® if:

- 1 You are in a coma.**
It may worsen coma state.
- 2 You are strongly under the influence of central nervous system (CNS) depressants, including barbiturate derivatives.**
Xeplion TRI® may intensify CNS depression.
- 3 You are taking clozapine or adrenaline (excluding use in emergency treatment for anaphylaxis and use in dental care for infiltrative anesthesia or nerve block).**
- 4 You have known hypersensitivity to paliperidone, risperidone, or any of the ingredients in Xeplion TRI®.**
- 5 You have moderate to severe kidney dysfunction (creatinine clearance < 50 mL/min).**

Before starting treatment
with Xeplion TRI®

At start

During treatment



Before you receive Xeplion TRI[®], be sure to tell your doctor or pharmacist if:

- 1** You have any other medical conditions (take or plan to take any other medicines).
- 2** You have previously experienced any allergic reactions to any medicines.
- 3** You have received or are currently receiving diabetes treatment.
- 4** You are pregnant, may be pregnant, or wish to become pregnant.
- 5** You are planning to undergo cataract surgery.



Precautions when you taking Xeplion TRI®



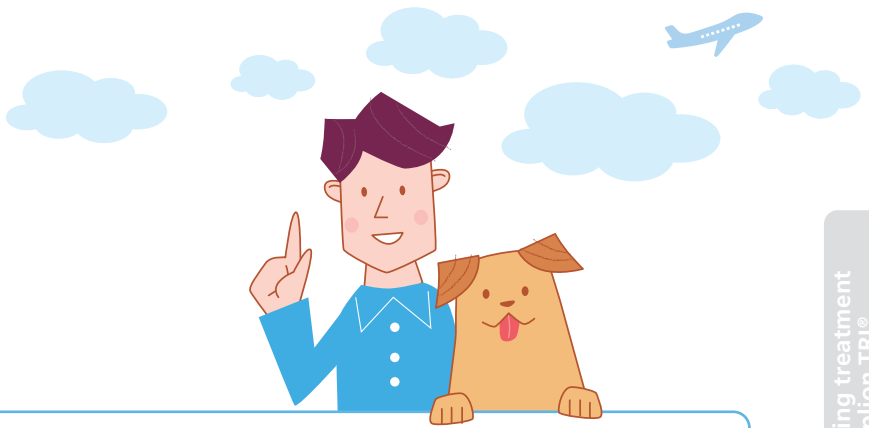
You must tell your doctor or pharmacist about all your medical conditions, including if:

- **You have complications or a medical history of any of the following:**
 - You have or are suspected to have cardiovascular disease or hypotension.
 - You have a history of arrhythmia or congenital long QT syndrome.
 - You have Parkinson's disease or Lewy body dementia.
 - You have or have a history of convulsive diseases such as epilepsy.
 - You have a history of attempted suicide and have suicidal thoughts.
 - You have diabetes, a history of diabetes, or risk factors of diabetes such as a family history of diabetes, high blood sugar, or obesity.
 - You have drug hypersensitivity.
 - You are debilitated from dehydration/malnutrition.
 - You are sedentary and do not move your body (muscles), or are in a long-term bedridden, obese, or dehydrated state.

Before starting treatment with Xeplion TRI®

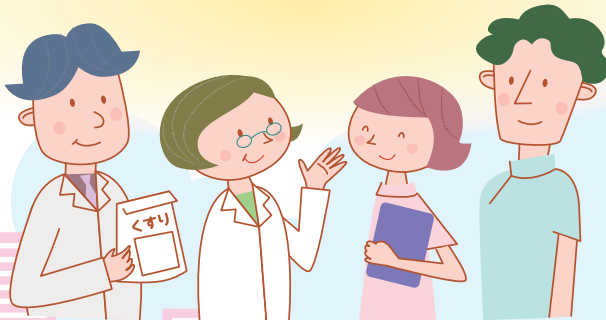
At start

During treatment



- You have mild, moderate, or severe kidney dysfunction.
- You have liver dysfunction.
- You are pregnant.
- You are a child.
- You are elderly.

If you meet any of the above criteria, make sure to consult with your doctor or pharmacist.



Precautions while receiving Xeplion TRI®



Please be careful about the following while receiving Xeplion TRI®.

1 Do not rub the injection site.

2 Refrain from heavy drinking as much as possible. Drinking alcohol may intensify the effects of the medicine.



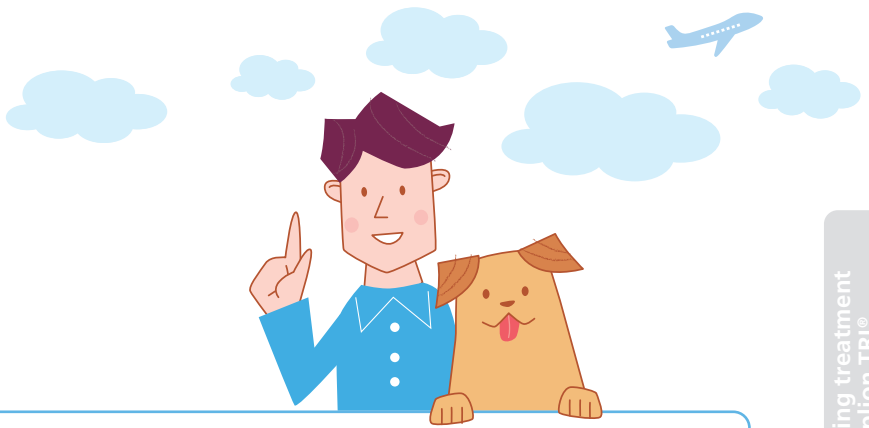
3 Do not drive or operate heavy machinery. This medicine may cause drowsiness or decreased attention/concentration.



Before starting treatment
with Xeplion TRI®

At start

During treatment



- 4** This medicine may cause hypoglycemia (low blood sugar).

If symptoms occur such as a feeling of weakness, fatigue, cold sweats, or fainting, make sure to tell your doctor or pharmacist.

- 5** If any symptoms of hyperglycemia (high blood sugar) occur, such as dry mouth, excessive water intake, or excessive or frequent urination, make sure to tell your doctor or pharmacist.

- 6** If you visit another clinic for another condition or purchase medications at a pharmacy, make sure to tell the doctor or pharmacist that you are currently receiving treatment with Xeplion TRI®.

* If you stop treatment with this medicine, be sure to tell the doctor or pharmacist who provided Xeplion TRI® treatment, regardless of when it was stopped.





What should I do?

Q What should I do if an injection is delayed?

A If you cannot attend a scheduled visit to your doctor, see your doctor as soon as possible.

* Ask your doctor for details on the dose if an injection is delayed.

Q How long should I receive injections?

A Even if you feel better, do not stop taking this medicine without consulting your doctor. Based on a medical examination, dose reduction should be considered and treatment that suppresses recurrence should be continued.

Q What are the possible side effects?

A If you experience any of the following side effects, tell your doctor or pharmacist. See pages 12 and 13 for more details of side effects.

Relatively common side effects of treatment with antipsychotic medications include:

- **Injection site pain or hardening**
(side effects of long-acting injections)
- **Difficulty sleeping or drowsiness**
- **Excitability or hostility**
- **Irresistible urge to move the legs, difficulty sitting still**

Q What should I do if I experience any side effects?

A Depending on your symptoms, the following approaches may be taken:

- **Symptomatic treatment**

Medications are used to suppress or alleviate your symptoms.

- **Adjustment of medication**

Xeplion TRI® is changed back to Xeplion®, stopped, or changed to another medicine to alleviate or resolve your symptoms.

- **Adjustment of environment**

Improvements are made in your eating habits or lifestyle to ameliorate your symptoms.

Q Are there any therapeutic approaches other than medicines?

A Other than treatment with medicines, there are language- or behavior-based approaches that attempt to bring about changes (psychosocial treatments):

- **Psychological treatment/counseling**

A doctor, clinical psychologist, or special staff such as a peer who receives the treatment similar to yours will hear your story and give you advice.

- **Psychiatric rehabilitation**

This treatment helps you to develop new skills through work activities or training.

Q If I have social problems, where should I go for a consultation?

A There are a support system or organization to support patients with schizophrenia and their families. See pages 14 and 15.

Side effects

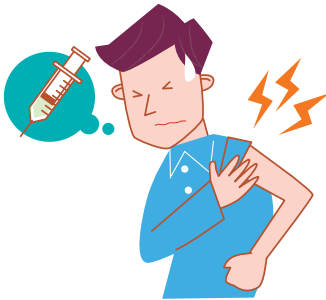
Possible side effects

If you experience any of the following symptoms, tell your doctor or pharmacist.

Relatively common side effects of antipsychotic medications

- **Injection site pain or hardening**

(side effects of long-acting injections)



- **Difficulty sleeping or drowsiness**



- **Worsened mental state such excitability or hostility**



- **Irresistible urge to move the legs, hard to sit still**



Side effects that require special attention

If you experience any of the following symptoms, tell your doctor or pharmacist as soon as possible:

- Sudden high fever, perspiration, increased saliva, difficulty swallowing, fast pulse, or muscle stiffness
- Protruding or retracting the lips, or sticking out the tongue
- Sudden feelings of bloating, or persistent constipation accompanied by abdominal pain and nausea
- Weight gain in a short period without edema
- Fever, rash, loss of appetite, or yellowing of skin or eyes
- Limb numbness and pain, muscle pain, or reddish-brown urine
- Palpitations, chest pain, or chest discomfort
- Headache or dizziness
- Thirst, excessive water intake, or excessive urination
- A feeling of weakness, fatigue (feeling tired), cold sweats, or hand tremors
- Having chills or a sore throat
- Shortness of breath or edema
- Prolonged erection that occurs regardless of sexual desire
- Anxiety or tingling sensation

Prepared based on Package Insert for Xeplion TRI® (11.1 Severe adverse reactions)

Other than the above, if any of unusual symptoms occurs, tell your doctor or pharmacist as soon as possible.



Social resources for supporting your recovery (self-realization)

Familiar social resources in your life

There are various systems that help people with schizophrenia visit the doctor, participate in social activities, and return to society.

For more details, consult with your doctor, psychiatric social worker, or the welfare division of the municipal office in the area where you live.



Financial support

▶ System of Medical Payment for Services and Supports for Persons with Disabilities

This is a support system in which the local government bears some of the hospital costs and medication costs when a person with a mental disorder receives outpatient care.

Support for social participation and social rehabilitation

▶ Mental Health and Welfare Center

The Center is an administrative body that provides comprehensive support, including support for participation in society, for patients with mental disorder, with the aim of sustaining and improving the mental health of local people.

投与スケジュールカード

ゼプリオン TRI®
を投与している方へ
12週に1回投与します

12週

氏名:

医療機関名:

医療機関の電話番号:
(緊急連絡先)

Introducing useful tools

- Carry your Dosing Schedule Card with you at all times.
- When you go to see a doctor, show the doctor or pharmacist this card and tell them that you take this medicine.

Other support

▶ Local family groups

Other people with schizophrenia and their families get together to talk about similar problems they have, and encourage and help one another. Activities generally take place at hospitals and public health centers. There are around 1600 family groups all over the country.

▶ Mental disability certificate (Certificate for persons with disabilities)

This is a certificate that individuals with a mental disorder show when receiving a variety of welfare services necessary for their daily life and social life.

Supporting organization in your neighborhood

*Provide here the contact information of a supporting organization in your neighborhood.

Name of the medical institute/contact information

Janssen Pharmaceutical K.K. / Sumitomo Pharma Co.,Ltd.