

For you who plan to start treatment with Xeplion TRI® and your family

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This pamphlet introduces a schizophrenia medicine (Xeplion TRI®). We believe you pursue recovery (self-realization). We hope you make good use of this pamphlet when communicating with individuals who support you— family, peers and healthcare professionals—.

About Xeplion TRI®



Dosing interval

Xeplion TRI®* is produced based on Xeplion® (4-weekly release intramuscular injection) by prolonging its effect to 12 weeks.

You will receive treatment with Xeplion TRI® once every 12 weeks.

* TRI is an abbreviation for twelve-weekly release injection.



If your dosing interval becomes 12 weeks, ...

The number of injections is decreased.



You can use more time for psychological treatment, etc.

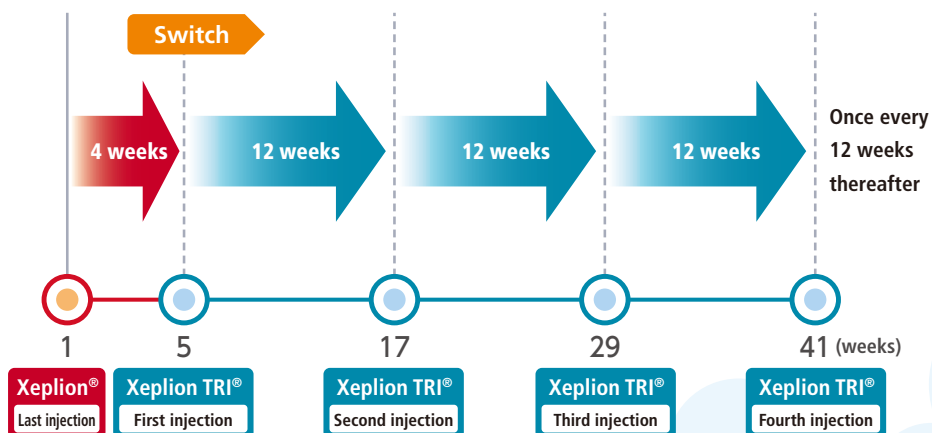
On the other hand, it may take longer to deal with any adverse reaction if it occurs. Also, your visit interval may be longer. You should consult with your doctor or healthcare professional to find visit frequency and means of communication (e.g., telephone, e-mail) which suit you.





Dosing schedule

The first injection of Xeplion TRI® is given 4 weeks after the last injection of Xeplion® (4-weekly release intramuscular injection). After that, you will be injected once every 12 weeks. Xeplion TRI® will be injected into either your buttock muscle (gluteal muscle) or 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 other antipsychotics.



Precautions before using Xeplion TRI®



Xeplion TRI® is not allowed to be used if you:

- 1 are in a coma**
It may worsen coma state.
- 2 are under strong influence of central nervous system (CNS) depressants including barbiturate derivatives**
It may intensify CNS depressant activity.
- 3 take adrenaline (excluding the use in emergent treatment for anaphylaxis or infiltration anesthesia or conduction anesthesia in the dental field) or clozapine**
- 4 have a known hypersensitivity to either paliperidone, risperidone, or any of the ingredients in Xeplion TRI®**
- 5 have moderate to severe kidney problems**
(creatinine clearance < 50 mL/min)

Before starting treatment
with Xeplion TRI®

At start

During treatment



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

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



Precautions when you start to receive Xeplion TRI®



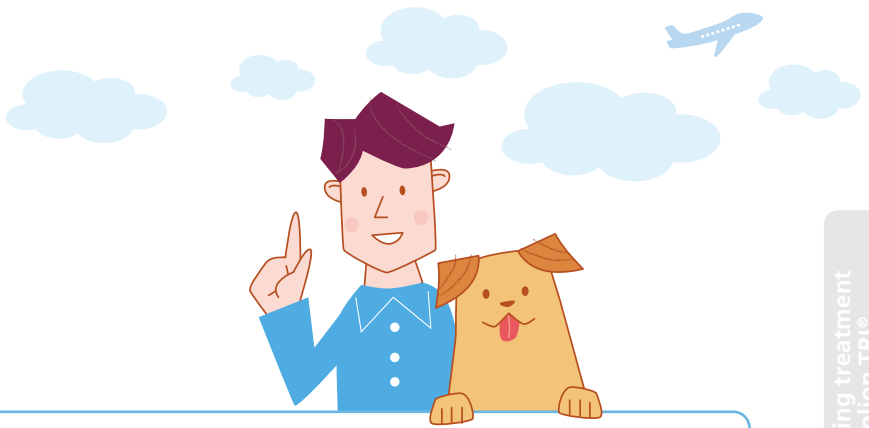
Before you receive Xeplion TRI®, tell your doctor or pharmacist about all your medical conditions, including if you:

- **have complications or a medical history of any of the following:**
 - have or are suspected of having cardiovascular disease or hypotension
 - have a history of arrhythmia
have congenital long QT syndrome
 - have Parkinson's disease or Lewy body dementia
 - have or have a history of convulsive diseases such as epilepsy
 - have a history of suicide attempt and have suicidal thought
 - have or have had diabetes, or
have risk factors of diabetes such as a family history of diabetes, high blood sugar or obesity
 - have drug hypersensitivity
 - are debilitated from dehydration/malnutrition
 - are still without moving your body (muscles),
are in a long-term bedridden, obese or in a dehydrated state

Before starting treatment
with Xeplion TRI®

At start

During treatment



● **have kidney problems**

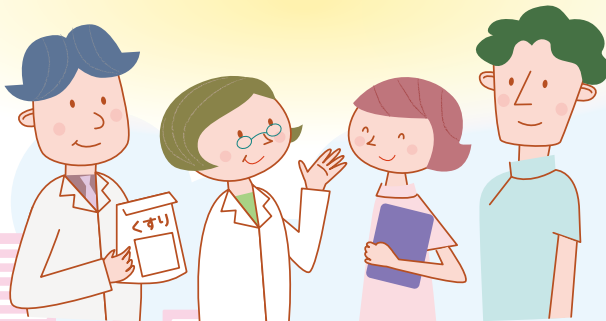
- moderate to severe kidney problems
- mild kidney problems

● **have liver problems**

- **are pregnant** ● **are a child** ● **are elderly**



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



Precautions while taking Xeplion TRI®



Pay attention to the following while you take Xeplion TRI®.

1 Do not rub the injection site.

2 Refrain from heavy drinking as much as possible. Drinking alcohol may intensify medicinal effects.



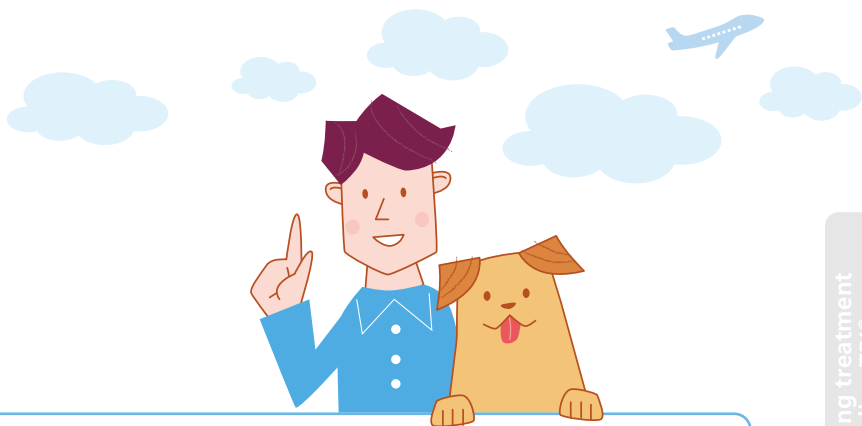
3 Do not drive, operate heavy machinery, or do other dangerous activities. This medicine may cause drowsiness or decreased attention/concentration.



Before starting treatment
with Xeplion TRI®

At start

During treatment



- 4** This medicine may cause hypoglycemia. If any of the symptoms—a feeling of weakness, fatigue, cold sweat or fainting—occurs, make sure to tell your doctor or pharmacist.
- 5** If any of the hyperglycemia symptoms such as dry mouth, excessive intake of water, excessive urination and frequent urination occurs, make sure to tell your doctor or pharmacist.
- 6** If you visit any other clinic for some other disease or purchase medications at any other pharmacy, make sure to tell the doctor or pharmacist that you receive treatment with Xeplion TRI®.

* If you stop treatment with this medicine, be sure to tell the doctor or pharmacist that you had received treatment with Xeplion TRI® regardless of timing for stopping the treatment.





What should I do?

Q What should I do if I have delayed injection?

A If you fail to go to see your doctor on the scheduled visit, go to see your doctor as early as possible.

* Ask your doctor for details on the given dose in case of delayed injection.

Q How long should I receive injection?

A Even if you feel better, do not stop taking medicine on your own judgment and be sure to consult with your doctor. Your doctor may need to consider dose reduction, or you need to continue treatment for suppressing recurrence based on medical examination.

Q What adverse reactions does this medicine develop?

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

The most common adverse reactions in antipsychotic medications

- **Injection site pain or hardening**
(commonly occurred adverse reactions of long-acting injections)
- **Difficulty sleeping, drowsiness**
- **Excitable, hostility**
- **Irresistible urge to move the legs, hard to sit still**



How should I do if I experience any adverse reactions?



There are the following approaches based on your symptoms:

- **Symptomatic treatment**

Use medications to suppress or alleviate your symptoms.

- **Adjustment of medicine**

Bring back to Xeplion®, stop Xeplion TRI®, or change to other medicine to alleviate or resolve your symptoms.

- **Adjustment of environment**

Improve your eating habit or lifestyle to ameliorate your symptoms.



Are there any other therapeutic approaches than medicines?



There are other approaches that cause change through language or behavior (psychosocial treatments) than treatment with medicines:

- **Psychological treatment/counseling**

A doctor, clinical psychotherapist or special staff such as your peer who receives the similar treatment as you take will hear your story and give you some advices.

- **Psychiatric rehabilitation**

A treatment to help develop new skills through work activities or training.



If I have social life problems, where should I consult?



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

About adverse reactions

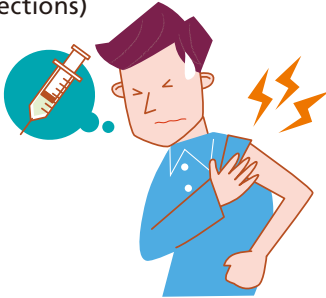
Possible adverse reactions

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

The most common adverse reactions in antipsychotic medications

- **Injection site pain or hardening**

(commonly occurred adverse reactions of long-acting injections)



- **Difficulty sleeping, drowsiness**



- **Worsened mental state such as being excitable or having hostility**



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



Adverse reactions to which especially you should pay attention

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

- Sudden high fever, perspiration, increased saliva, difficulty swallowing, fast pulse and muscle stiffness
- Protruding or retracting the lips, sticking out the tongue
- The stomach feels bloated suddenly, persistent constipation and accompanied abdominal pain and nausea
- Weight gain for a short period without edema
- Fever, rash, loss of appetite, yellow skin or eyes
- Limb numbness and pain, muscle pain, and urine turns a reddish-brown color
- Palpitation, chest pain and chest discomfort
- Headache, dizziness
- Thirst, excessive intake of water and excessive urination
- A feeling of weakness, fatigue (feel tired), cold sweat and hand tremors
- Have chills, sore throat
- Breath shortness, edema
- Prolonged erection that occurs regardless of sexual desire
- Anxiety, tingling sensation

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

If any of the different symptoms other than the above ones occurs, tell your doctor or pharmacist as early as possible.



Social resources for supporting your recovery (self-realization)

Familiar social resources in your life

There are a variety of systems to help patients with schizophrenia go to see a doctor or participate in social activities or 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 cost or medication cost when a person with mental disorder receives outpatient care.

Support of social participation and social rehabilitation

▶ Mental Health and Welfare Center

The Center is an administrative body to aim at sustaining and improving mental health of local people as well as to support social participation of patients with mental disorder comprehensively.



Introduction of 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 him or her that you take this medicine.

Other support

▶ Local federation of families

Patients with the same disease and their families get together to talk the same suffering one another, encourage and help one another. Hospitals and public health center take leadership in these activities. There are around 1600 federations of families all over the country.

▶ Mental disability certificate (disability certificate)

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

Supporting organization in the neighborhood

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

For individuals who wish to learn more about
schizophrenia



※ This site is only available in Japanese.

<https://www.mental-navi.net/togoshicchosho/>



Medical institute/contact information