

PATIENT MEDICATION INFORMATION (TREMIFYA®)

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTREMIFYA®

(guselkumab injection)

Solution for injection

100 mg/1 mL pre-filled syringe

100 mg/1 mL TREMIFYA One-Press® (patient-controlled injector)

200 mg/2 mL pre-filled syringe

200 mg/2 mL pen

Read this carefully before you start taking **TREMIFYA®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TREMIFYA®**.

What is TREMIFYA® used for?

- **Plaque Psoriasis**

TREMIFYA® is a prescription medicine used to treat adults with moderate to severe “plaque psoriasis”, an inflammatory condition affecting the skin and nails. Plaque psoriasis can cause raised, thick, red and scaly patches (“psoriatic lesions”) that can appear anywhere on your body. TREMIFYA® reduces the inflammation and other symptoms of the disease.

- **Psoriatic Arthritis**

TREMIFYA® is used to treat adults with active psoriatic arthritis. Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. Psoriatic arthritis can cause pain, swelling and stiffness in the joints, in addition to a disruption in daily activities and fatigue. If you have active psoriatic arthritis, you will be given TREMIFYA® alone or in combination with a conventional Disease Modifying Anti-Rheumatic Drug (cDMARD) such as methotrexate. TREMIFYA® reduces signs and symptoms of your arthritis and may improve symptoms in patients that have psoriasis.

- **Crohn’s Disease**

TREMIFYA® is used to treat adults with moderately to severely active Crohn’s disease, an inflammatory disease of the bowel. Using TREMIFYA® in Crohn’s disease can benefit you by reducing the signs and symptoms of the disease such as diarrhea, abdominal pain, and the inflammation of your intestinal lining. This may enable your normal daily activities and reduce fatigue.

- **Ulcerative Colitis**

TREMIFYA® is used to treat adults with moderately to severely active ulcerative colitis, an inflammatory disease of the bowel. Using TREMIFYA® in ulcerative colitis will benefit you by reducing the signs and symptoms of the disease including bloody stools, the need to rush to

and the number of times you go to the toilet, abdominal pain and the inflammation of your intestinal lining. This may enable your normal daily activities and reduce fatigue.

How does TREMFYA® work?

TREMFYA® contains the active substance guselkumab. Guselkumab is a monoclonal antibody. Monoclonal antibodies are proteins that recognize and bind specifically to certain proteins in the body. This medicine works by neutralizing the activity of a protein called IL-23, which is present at increased levels in diseases such as plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis.

Using TREMFYA® should improve your skin clearance and reduce your symptoms of psoriasis such as itching, pain, stinging, burning and skin tightness. In addition, TREMFYA® helps reduce the signs and symptoms of psoriatic arthritis.

What are the ingredients in TREMFYA®?

Medicinal ingredients: guselkumab

Non-medicinal ingredients: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection.

TREMFYA® comes in the following dosage forms:

Pre-filled syringe:

- 100 mg in 1 mL of solution for injection in a single-dose pre-filled syringe
- 200 mg in 2 mL of solution for injection in a single-dose pre-filled syringe

Pen:

- 200 mg in 2 mL of solution for injection in a single-dose pre-filled pen

TREMFYA One-Press®:

- 100 mg in 1 mL of solution for injection in a single-dose patient-controlled injector

Do not use TREMFYA® if:

- You are allergic to guselkumab or any of the ingredients in TREMFYA®. See **What are the ingredients in TREMFYA®**.

If you think you are allergic, ask your healthcare professional for advice before using TREMFYA®.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TREMFYA®. Talk about any health conditions or problems you may have, including if you:

- are being treated for an infection or if you have an infection that does not go away or keeps coming back. TREMFYA® may lower your ability to fight infections and may increase your risk of infections.
- have tuberculosis (TB) or have been in close contact with someone with TB.
- think you have an infection or have symptoms of an infection such as
 - fever or flu-like symptoms

- muscle aches
- cough
- shortness of breath
- burning when you urinate or urinating more often than normal
- blood in your phlegm (mucus)
- weight loss
- warm, red or painful skin or sores on your body different from your psoriasis
- diarrhea or stomach pain
- have recently had a vaccination or if you are due to have a vaccination during treatment with TREMFYA®. You should not be given certain types of vaccines (live vaccines) while using TREMFYA®.
- are pregnant, think that you may be pregnant or are planning to have baby. If you are a woman of childbearing potential, use adequate contraception while using TREMFYA® and for at least 12 weeks after the last TREMFYA® dose. Talk to your healthcare professional about your contraception options.
- are breast-feeding or plan to breast-feed. You and your healthcare professional should decide if you will breast-feed while using TREMFYA®.

Look out for infections and allergic reactions

- Do not use TREMFYA® if you have any symptoms of infection unless you are instructed by your healthcare provider.
- **After starting TREMFYA®, call your healthcare provider right away if you have any of the symptoms of an infection listed above.**
- **Serious allergic reactions, which can include symptoms of a swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing, hives and shortness of breath, have occurred with TREMFYA®. Tell your healthcare professional or seek medical help immediately if you experience these symptoms.**

Children and adolescents (below the age of 18 years)

TREMFYA® is not recommended for children and adolescents (under 18 years of age) because it has not been studied in this age group.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take TREMFYA®:

Always use this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

TREMFYA® is given by injection under your skin (subcutaneous injection).

You and your healthcare professional should decide if you should inject TREMFYA® yourself. It is important not to try to inject yourself until you have been trained by your healthcare professional. A caregiver may also give you your TREMFYA® injection after proper training.

Before use, take the carton out of the refrigerator and allow it to reach room temperature by waiting 30 minutes. Keep the TREMFYA® pre-filled syringe, pen, or TREMFYA One-Press® patient-controlled injector in the carton to protect from light.

Read the “Instructions for Use” document carefully before using TREMFYA®.

Usual dose:

Your healthcare professional will decide how much TREMFYA® you need and for how long.

Plaque Psoriasis

- The dose is 100 mg by subcutaneous injection.
- The first dose may be given by your healthcare provider.
- After the first dose, you will have the next dose 4 weeks later, followed by a dose every 8 weeks.

Psoriatic Arthritis

- The dose is 100 mg by subcutaneous injection.
- The first dose may be given by your healthcare provider.
- After the first dose, you will have the next dose 4 weeks later, followed by a dose every 8 weeks.

Crohn’s Disease

Treatment start

Treatment start can be given by either intravenous infusion (drip in a vein in your arm) or administered subcutaneously (injections under the skin).

Intravenous Infusion (TRMFYA® I.V.):

- The first dose is 200 mg and will be given by your healthcare provider by intravenous infusion over at least 1 hour (refer to the Patient Medication Information for TREMFYA® I.V.).
- After the first dose, you will have the second dose by intravenous infusion 4 weeks later, and then a third dose by intravenous infusion after an additional 4 weeks.

Subcutaneous administration (TRMFYA®):

- The first dose is 400 mg and will be given by injections under the skin at different locations of the body.
- After the first dose, you will have a second 400 mg dose 4 weeks later and then a third 400 mg dose after an additional 4 weeks.

Maintenance therapy (TRMFYA®)

A maintenance dose will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg. Your healthcare provider will decide which maintenance dose you will receive:

- A dose of 100 mg will be given 8 weeks after the third treatment start dose, followed by a dose every 8 weeks.
- A dose of 200 mg will be given 4 weeks after the third treatment start dose, followed by a dose every 4 weeks.

Ulcerative Colitis

Treatment start (TREMFYA® I.V.)

- The first dose is 200 mg and will be given by your healthcare provider by intravenous infusion (drip in a vein in your arm) over at least 1 hour (refer to the Patient Medication Information for TREMFYA® I.V.).
- After the first dose, you will have the second dose by intravenous infusion 4 weeks later, and then a third dose by intravenous infusion after an additional 4 weeks.

Maintenance therapy (TREMFYA®)

A maintenance dose will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg. Your healthcare provider will decide which maintenance dose you will receive:

- A dose of 100 mg will be given 8 weeks after the third treatment start dose, followed by a dose every 8 weeks.
- A dose of 200 mg will be given 4 weeks after the third treatment start dose, followed by a dose every 4 weeks.

TREMFYA® is for long-term treatment. Your healthcare professional will regularly monitor your condition to check that the treatment is having the desired effect.

You should not stop using TREMFYA® unless you think it is causing a severe side effect. Speak to your healthcare professional as soon as possible if this happens.

Overdose:

If you accidentally inject more TREMFYA® than you should or the dose has been given sooner than prescribed, inform your healthcare professional.

If you think you have taken too much TREMFYA®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you forget to take your TREMFYA® dose, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. If you are not sure what to do, contact your healthcare professional.

What are possible side effects from using TREMFYA®?

As with all medicines, this medicine can cause side effects, although not everybody gets them.

Most of the following side effects are mild to moderate. If any of these side effects becomes severe, tell your healthcare professional.

Some side effects are very common (may affect more than 1 in 10 people)

- Infections of the nose, sinuses, or throat (e.g. common cold) or chest infections (bronchitis)

Some side effects are common (may affect up to 1 in 10 people):

- Redness, pain, irritation, swelling, bruising and/or itching at the injection site
- diarrhea
- headache
- joint pain
- increased level of liver enzymes in the blood

Some side effects are uncommon (may affect up to 1 in 100 people):

- stomach flu (gastroenteritis)
- herpes simplex infections (e.g. cold sores, genital herpes)
- fungal infections of the skin (e.g. athlete's foot)
- migraine
- yeast infections
- allergic reactions
- skin rash
- decreased number of a type of white blood cell called neutrophils

These are not all the possible side effects you may feel when taking TREMFYA®. If you experience any side effects not listed here, contact your healthcare professional.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store TREMFYA® in the refrigerator between 2°C to 8°C (36°F to 46°F).

Do not freeze. Do not use if TREMFYA® has been frozen.

Do not shake TREMFYA®.

Store in original packaging to protect from light until use.

Keep out of reach and sight of children.

Do not use TREMFYA®:

- if you notice that it is damaged or the seal is broken.
- if the liquid is discoloured, cloudy or you can see large particles floating in it.
- after the expiry date which is stated on the label and on the outer carton after “EXP.”

TREMFYA® is for single use only. Ask your healthcare professional how to throw away medicines that are no longer required.

If you want more information about TREMFYA®:

- Talk to your healthcare professional
- For questions or concerns, contact the manufacturer, Janssen Inc. (www.janssen.com/canada)
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer’s website www.janssen.com/canada, or by contacting the manufacturer at: 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by Janssen Inc., Toronto, Ontario, M3C 1L9.

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PATIENT MEDICATION INFORMATION (TREMFYA® I.V.)

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

TREMFYA® I.V.

(guselkumab for injection)

Solution for intravenous injection

200 mg/ 20 mL

Read this carefully before you start taking **TREMFYA® I.V.** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TREMFYA® I.V.**

What is TREMFYA® I.V. used for?

- **Crohn's Disease**

TREMFYA® I.V. is used to treat adults with moderately to severely active Crohn's disease, an inflammatory disease of the bowel. Using TREMFYA® I.V. in Crohn's disease can benefit you by reducing the signs and symptoms of the disease such as diarrhea, abdominal pain, and the inflammation of your intestinal lining. This may enable your normal daily activities and reduce fatigue.

- **Ulcerative Colitis**

TREMFYA® I.V. is used to treat adults with moderately to severely active ulcerative colitis, an inflammatory disease of the bowel. Using TREMFYA® I.V. in ulcerative colitis will benefit you by reducing the signs and symptoms of the disease including bloody stools, the need to rush to and the number of times you go to the toilet, abdominal pain and the inflammation of your intestinal lining. This may enable your normal daily activities and reduce fatigue.

How does TREMFYA® I.V. work?

TREMFYA® I.V. contains the active substance guselkumab. Guselkumab is a monoclonal antibody. Monoclonal antibodies are proteins that recognize and bind specifically to certain proteins in the body. This medicine works by neutralizing the activity of a protein called IL-23, which is present at increased levels in diseases such as Crohn's disease and ulcerative colitis.

What are the ingredients in TREMFYA® I.V.?

Medicinal ingredients: guselkumab

Non-medicinal ingredients: EDTA disodium dihydrate, L-histidine, L-histidine monohydrochloride monohydrate, L-methionine, polysorbate 80, sucrose and water for injection.

TREMFYA® I.V. comes in the following dosage forms:

TREMFYA® I.V. is supplied as a 200 mg/20 mL (10mg/mL) solution in a single-dose vial.

Do not use TREMFYA® I.V. if:

- You are allergic to guselkumab or any of the ingredients in TREMFYA®/TRMFYA® I.V. See **What are the ingredients in TREMFYA® I.V.**

If you think you are allergic, ask your healthcare professional for advice before using TREMFYA® I.V.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TREMFYA® I.V. Talk about any health conditions or problems you may have, including if you:

- are being treated for an infection or if you have an infection that does not go away or keeps coming back. TREMFYA® I.V. may lower your ability to fight infections and may increase your risk of infections.
- have tuberculosis (TB) or have been in close contact with someone with TB.
- think you have an infection or have symptoms of an infection such as
 - fever or flu-like symptoms
 - muscle aches
 - cough
 - shortness of breath
 - burning when you urinate or urinating more often than normal
 - blood in your phlegm (mucus)
 - weight loss
 - warm, red or painful skin or sores on your body
 - diarrhea or stomach pain
- have recently had a vaccination or if you are due to have a vaccination during treatment with TREMFYA® I.V. You should not be given certain types of vaccines (live vaccines) while using TREMFYA®/TRMFYA® I.V.
- are pregnant, think that you may be pregnant or are planning to have baby. If you are a woman of childbearing potential, use adequate contraception while using TREMFYA®/TRMFYA® I.V. and for at least 12 weeks after the last TREMFYA®/TRMFYA® I.V. dose. Talk to your healthcare professional about your contraception options.
- are breast-feeding or plan to breast-feed. You and your healthcare professional should decide if you will breast-feed while using TREMFYA®/TRMFYA® I.V.

Look out for infections and allergic reactions

- Do not use TREMFYA® I.V. if you have any symptoms of infection unless you are instructed by your healthcare provider.
- **After starting TREMFYA® I.V., call your healthcare provider right away if you have any of the symptoms of an infection listed above.**
- **Serious allergic reactions, which can include symptoms of a swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing, hives and shortness of breath, have occurred with TREMFYA® I.V. Tell your healthcare professional or seek medical help immediately if you experience these symptoms.**

Children and adolescents (below the age of 18 years)

TREMFYA® I.V. is not recommended for children and adolescents (under 18 years of age) because it has not been studied in this age group.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take TREMFYA® I.V.:

TREMFYA® I.V. will be given by your healthcare professional.

Usual dose:

Crohn's Disease

Treatment start

Treatment start can be given by either intravenous infusion (drip in a vein in your arm) or administered subcutaneously (injections under the skin).

Intravenous Infusion (TREMFYA® I.V.):

- The first dose is 200 mg and will be given by your healthcare provider by intravenous infusion over at least 1 hour.
- After the first dose, you will have the second dose by intravenous infusion 4 weeks later, and then a third dose by intravenous infusion after an additional 4 weeks.

Subcutaneous administration (TREMFYA®):

- The first dose is 400 mg and will be given by injections under the skin at different locations of the body (refer to the Patient Medication Information for TREMFYA®).
- After the first dose, you will have a second 400 mg dose 4 weeks later and then a third 400 mg dose after an additional 4 weeks.

Maintenance therapy (TREMFYA®)

A maintenance dose will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg (refer to the Patient Medication Information for TREMFYA®). Your healthcare provider will decide which maintenance dose you will receive:

- A dose of 100 mg will be given 8 weeks after the third treatment start dose, followed by a dose every 8 weeks.
- A dose of 200 mg will be given 4 weeks after the third treatment start dose, followed by a dose every 4 weeks.

Ulcerative Colitis

Treatment start (TREMFYA® I.V.)

- The first dose is 200 mg and will be given by your healthcare provider by intravenous infusion (drip in a vein in your arm) over at least 1 hour.
- After the first dose, you will have the second dose by intravenous infusion 4 weeks later, and then a third dose by intravenous infusion after an additional 4 weeks.

Maintenance therapy (TREMFYA®)

A maintenance dose will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg (refer to the Patient Medication Information for TREMFYA®). Your healthcare provider will decide which maintenance dose you will receive:

- A dose of 100 mg will be given 8 weeks after the third treatment start dose, followed by a dose every 8 weeks.
- A dose of 200 mg will be given 4 weeks after the third treatment start dose, followed by a dose every 4 weeks.

Your healthcare professional will regularly monitor your condition to check that the treatment is having the desired effect.

You should not stop using TREMFYA® I.V. unless you think it is causing a severe side effect. Speak to your healthcare professional as soon as possible if this happens.

Overdose:

In the event of overdosage, monitor the patient for any signs or symptoms of adverse reactions and administer appropriate symptomatic treatment immediately.

If you think you have taken too much TREMFYA® I.V., contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you forget or miss an appointment to receive TREMFYA® I.V., contact your healthcare professional.

What are possible side effects from using TREMFYA® I.V.?

As with all medicines, this medicine can cause side effects, although not everybody gets them.

Most of the following side effects are mild to moderate. If any of these side effects becomes severe, tell your healthcare professional.

Some side effects are very common (may affect more than 1 in 10 people)

- Infections of the nose, sinuses, or throat (e.g. common cold) or chest infections (bronchitis)

Some side effects are common (may affect up to 1 in 10 people):

- Redness, pain, irritation, swelling, bruising and/or itching at the injection site
- diarrhea
- headache
- joint pain
- increased level of liver enzymes in the blood

Some side effects are uncommon (may affect up to 1 in 100 people):

- stomach flu (gastroenteritis)
- herpes simplex infections (e.g. cold sores, genital herpes)
- fungal infections of the skin (e.g. athlete's foot)
- migraine
- yeast infections
- allergic reactions
- skin rash
- decreased number of a type of white blood cell called neutrophils

These are not all the possible side effects you may feel when taking TREMFYA® I.V. If you experience any side effects not listed here, contact your healthcare professional.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store TREMFYA® I.V. in the refrigerator between 2°C to 8°C (36°F to 46°F).

Do not freeze. Do not use if TREMFYA® I.V. has been frozen.

Do not shake TREMFYA® I.V.

Store in original packaging to protect from light until use.

Keep out of reach and sight of children.

Do not use TREMFYA® I.V.:

- if you notice that it is damaged or the seal is broken.
- if the liquid is discoloured, cloudy or you can see large particles floating in it.
- after the expiry date which is stated on the label and on the outer carton after “EXP.”

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If you want more information about TREMFYA® I.V.:

- Talk to your healthcare professional
- For questions or concerns, contact the manufacturer, Janssen Inc. (www.janssen.com/canada)
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer’s website www.janssen.com/canada, or by contacting the manufacturer at: 1-800-567-3331 or 1-800-387-8781.

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