

VOYDEYA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I taking Voydeya?

Voydeya contains the active ingredient danicopan. Voydeya has been designed to block a protein called factor D, which is a part of the body's defense system called the 'complement system'. Voydeya prevents your body's immune system from destroying your red blood cells outside of the vascular system (extravascular haemolysis). For more information, see Section [1. Why am I using Voydeya?](#) in the full CMI.

2. What should I know before I take Voydeya?

Do not use if you have ever had an allergic reaction to danicopan or any of the ingredients listed at the end of the CMI.

Voydeya is a medicine that affects your body's defense system and so can lower the ability of your immune system to fight infections. Using this medicine may increase your risk of severe infection. Before taking Voydeya as an add on to eculizumab or ravulizumab ensure that your meningococcal vaccination status is up to date. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Voydeya?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Voydeya and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take Voydeya?

- The recommended starting dose of Voydeya is 150 mg three times a day, approximately 8 hours apart (plus or minus 2 hours). Your doctor may decide to increase the dosage to 200 mg three times a day depending on how you respond to treatment.
- Depending on the dose prescribed, the number of tablets is as follows:
 - Dose 150 mg: take one film-coated tablet of 50 mg and one film-coated tablet of 100 mg three times a day

- Dose 200 mg: take two film-coated tablets of 100 mg three times a day.

More instructions can be found in Section [4. How do I use Voydeya?](#) in the full CMI.

5. What should I know while taking Voydeya?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Voydeya.• Talk to your doctor before you start taking this medicine to be sure that you are up-to-date with your vaccinations against <i>Neisseria meningitidis</i>.
Things you should not do	<ul style="list-style-type: none">• Do not take Voydeya if you are allergic to danicopan or any of the ingredients of this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Store in the original container.• Store below 30°C.

For more information, see Section [5. What should I know while using Voydeya?](#) in the full CMI.

6. Are there any side effects?

Voydeya targets the complement system, which is part of the body's defense against infections, the use of this medicine may increase your risk of meningococcal infection caused by *Neisseria meningitidis*. These are severe infections affecting the lining of the brain which can cause inflammation of the brain (encephalitis) and can spread throughout the blood and body (sepsis). If you do experience any meningococcal infection symptoms (see Section [2. What should I know before I take Voydeya?](#) for a list of symptoms) you should immediately contact your doctor or nurse. Voydeya can also increase your risk of other serious infections. Other common side effects of Voydeya include headache, vomiting, nausea, fever, joint, arm and leg pain, high blood pressure, physical weakness, diarrhoea, and blood tests showing increased levels of liver enzymes. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Voydeya[®] (Voy-day-ah)

Active ingredient(s): *Danicopan* (Dan-i-co-pan)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Voydeya. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Voydeya.

Where to find information in this leaflet:

- [1. Why am I using Voydeya?](#)
- [2. What should I know before I use Voydeya?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Voydeya?](#)
- [5. What should I know while using Voydeya?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking Voydeya?

Voydeya contains the active ingredient danicopan. Danicopan has been designed to block a protein called factor D, which is a part of the body's defence system called the 'complement system'. Danicopan prevents your body's immune system from destroying your red blood cells outside of the vascular system (extravascular haemolysis).

Voydeya is used to treat signs or symptoms of extravascular haemolysis in adult patients with a disease called paroxysmal nocturnal haemoglobinuria (PNH) during treatment with another type of PNH medicine called a C5 inhibitor (ravulizumab or eculizumab). You will be given Voydeya in addition to your current PNH medicine (ravulizumab or eculizumab).

The signs or symptoms of extravascular haemolysis are anaemia and related symptoms such as tiredness, difficulty in functioning, and shortness of breath.

When given in addition to your current PNH medicine (ravulizumab or eculizumab), Voydeya has been shown to improve the signs or symptoms of anaemia, such as fatigue, and reduce the need for blood transfusions.

2. What should I know before I take Voydeya?

Warnings

Do not use Voydeya if:

- you are allergic to danicopan, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- your history of vaccination is unknown or if you are not up-to-date on your meningococcal vaccines as per local guidelines.
- you have meningococcal infection.

Check with your doctor if you:

- have any other medical conditions such as meningococcal infections or *Neisseria* infections.
- take any medicines for any other condition.

Meningococcal and other *Neisseria* infections symptoms

Because the medicine targets the complement system, which is part of the body's defences against infection, the use of this medicine may increase your risk of meningococcal infection caused by *Neisseria meningitidis*. These are severe infections affecting the linings of the brain and can spread throughout the blood and body (sepsis).

Talk to your doctor before you start taking this medicine to be sure that you are up-to-date with your vaccinations against *Neisseria meningitidis*. If you have had these vaccines in the past, you might still need additional vaccinations (i.e., booster) before starting this medicine. These vaccinations should be given at least 2 weeks before starting this medicine. If you cannot be vaccinated 2 weeks beforehand, your doctor will prescribe antibiotics to reduce the risk of infection for 2 weeks after you have been vaccinated.

Meningococcal infection symptoms

If you experience any of the following symptoms, you should immediately inform your doctor:

- headache with nausea or vomiting
- headache and fever
- headache with a stiff neck or stiff back
- fever
- fever and rash
- confusion
- muscle aches with flu-like symptoms
- eyes sensitive to light

Voydeya is a medicine that affects your body's defense system and so can lower the ability of your immune system to fight infections. Using this medicine may increase your risk of severe infection. Before taking Voydeya as an add on to eculizumab or ravulizumab ensure that your meningococcal vaccination status is up to date.

Blood tests

Voydeya may increase the amount of some liver enzymes in your blood. Your doctor may do some blood tests to check your liver before starting treatment. Your doctor may continue to do blood tests to check your liver function after treatment has been initiated. Your doctor will explain this to you. Voydeya is not recommended in patients with severe hepatic impairment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The effects of the medicine on an unborn child are not known. As a precautionary measure, you should not be given Voydeya if you are pregnant. The use of effective contraception methods is recommended during treatment by women who are able to get pregnant. Ask your doctor or pharmacist for advice before taking this medicine.

Children and adolescents

Do not give this medicine to children under 18 years of age as no data are available on its safety and effectiveness in this age group.

Voydeya contains lactose monohydrate

If you are intolerant to some sugars (lactose), contact your doctor before taking this medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Voydeya and affect how it works.

- Medicines used to thin the blood [dabigatran and edoxaban].
- Medicine used to treat irregular heartbeats (arrhythmia) and weakness of the heart (heart failure) [digoxin].
- Medicines used to relieve allergy symptoms [fexofenadine].
- Medicines used to prevent your liver, kidney, lung, or heart from being attacked or rejected by your body after a transplant [tacrolimus].
- Medicines used to lower high cholesterol [rosuvastatin].
- Medicines used to treat rheumatoid arthritis, ulcerative colitis, Crohn's disease [sulfasalazine].

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Voydeya.

4. How do I take Voydeya?

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

The recommended starting dose of Voydeya is 150 mg three times a day, approximately 8 hours apart (plus or minus 2 hours). Your doctor may decide to increase the dosage to 200 mg three times a day depending on how you respond to treatment.

Depending on the dose prescribed, the number of tablets is as follows:

- Dose 150 mg: take one film-coated tablet of 50 mg and one film-coated tablet of 100 mg three times a day
- Dose 200 mg: take two film-coated tablets of 100 mg three times a day

When to take Voydeya

- You can take your tablets with or without food.

Voydeya should be taken in addition to your current PNH medicine (ravulizumab or eculizumab).

If you forget to take Voydeya

Voydeya should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as possible. If it is almost time to take your next dose, skip the missed dose. Then take the next dose at the normal time. Do not take a double dose to make up for a missed dose.

If you use too much Voydeya

If you think that you have used too much Voydeya, you may need urgent medical attention. Contact your doctor immediately. Take the medicine pack with you so that you can easily describe what you have taken.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Voydeya?

Things you should do

Talk to your doctor before you start taking this medicine to be sure that you are up-to-date with your vaccinations against *Neisseria meningitidis*. If you have had these vaccines in the past, you might still need additional vaccinations (i.e., booster) before starting this medicine. These vaccinations should be given at least 2 weeks before starting this medicine. If you cannot be vaccinated 2 weeks beforehand, your doctor will prescribe antibiotics to reduce the risk of infection for 2 weeks after you have been vaccinated.

Your doctor may continue to do blood tests to check your liver function after treatment has been initiated.

Call your doctor straight away if you experience any of the following symptoms:

- headache and fever
- headache with a stiff neck or stiff back
- fever
- fever and rash
- confusion
- muscle aches with flu-like symptoms
- eyes sensitive to light

Remind any doctor, dentist or pharmacist you visit that you are using Voydeya.

Things you should not do

Do not stop using this medicine suddenly. PNH is a lifelong condition and so it is expected that you will use this medicine for a long time. Do not stop treatment with Voydeya unless your doctor tells you to. If you stop taking this medicine, you may be at risk of developing signs and symptoms of extravascular haemolysis. If you have to stop taking this medicine, your doctor will reduce the dose gradually.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Voydeya affects you.

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

Drinking alcohol

Tell your doctor if you drink alcohol.

The effects of this medicine when drinking alcohol were not assessed as part of its registration.

Looking after your medicine

- Store in the original container.
- Store below 30°C.

- Keep Voydeya in the pack until it is time to use it. If you take the tablets out of the pack, they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop using this medicine, or the expiry date has passed, ask your pharmacist what to do with any that is left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Headache ● Vomiting ● Diarrhoea ● Fatigue ● Nausea ● Fever or high temperature (pyrexia) ● Joint pain ● Physical weakness ● Arm and leg pain (pain in extremities) ● High blood pressure 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● Blood test showing increased liver enzymes ● Meningococcal infection <ul style="list-style-type: none"> ○ Headache with nausea or vomiting 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ○ Headache with a stiff neck or stiff back ○ Fever ○ Fever and rash ○ Confusion ○ Muscle aches with flu-like symptoms ○ Eyes sensitive to light 	<p>notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Voydeya contains

Active ingredient (main ingredient)	Danicopan
Other ingredients (inactive ingredients)	Lactose monohydrate Microcrystalline cellulose Croscarmellose sodium Sodium lauryl sulfate Magnesium stearate Colloidal anhydrous silica Hypromellose acetate succinate Polyvinyl alcohol Titanium dioxide Macrogol/polyethylene glycol Purified Talc
Potential allergens	Not applicable

Do not take this medicine if you are allergic to any of these ingredients.

What Voydeya looks like

Voydeya 50 mg film-coated tablets

White to off-white, round film-coated tablets, "DCN" above "50" debossed on one side, plain on the other side.

Voydeya 100 mg film-coated tablets

White to off-white, round film-coated tablets, "DCN" above "100" debossed on one side, plain on the other side.

(50 mg + 100 mg Bottle -Aust R 416091)

(50 mg + 100 mg Blister -Aust R 416092*)

(100 mg Bottle -Aust R 416090)

(100 mg Blister -Aust R 416093*)

*Presentations not available.

Who distributes Voydeya

In Australia Voydeya is registered by:

Alexion Pharmaceuticals Australasia Pty Ltd

Level 4, 66 Talavera Road,

Macquarie Park, NSW, 2113

Medical enquiries: 1800 788 189

This leaflet was prepared in November 2024.