

# INQOVI® 35/100

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## 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.

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

## 1. Why am I using INQOVI 35/100?

INQOVI 35/100 contains the active ingredients decitabine and cedazuridine. INQOVI 35/100 is used to treat myelodysplastic syndrome (MDS) or chronic myelomonocytic leukaemia (CMML). For more information, see Section [1. Why am I using INQOVI 35/100?](#) in the full CMI.

## 2. What should I know before I use INQOVI 35/100?

Do not use if you have ever had an allergic reaction to INQOVI 35/100 or any of the ingredients listed at the end of the CMI.

**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 INQOVI 35/100?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with INQOVI 35/100 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 use INQOVI 35/100?**

- Always take this medicine exactly as your doctor or pharmacist has told you
- Take one tablet daily on the first five days of each 28 day treatment cycle or as directed by your doctor.
- Swallow the tablets whole on an empty stomach with a full glass of water, and avoid eating at least 2 hours before and 2 hours afterwards. Do not chew or break the tablets.

More instructions can be found in Section [4. How do I use INQOVI 35/100?](#) in the full CMI.

## 5. What should I know while using INQOVI 35/100?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● Remind any doctor, dentist or pharmacist you visit that you are using INQOVI 35/100.</li><li>● Call your doctor straight away if you feel very unwell, have a fever and chills, bleed or bruise easily</li><li>● Keep all your doctor's appointments so that your progress can be checked</li><li>● Use contraception while undergoing treatment.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● Do not stop using this medicine without talking to your doctor</li><li>● Do not give your medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>● Be careful before you drive or use any machines or tools until</li></ul>

	you know how INQOVI 35/100 affects you.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store below 25°C.</li> </ul>

For more information, see Section [5. What should I know while using INQOVI 35/100?](#) in the full CMI.

## **6. Are there any side effects?**

The most common side effects are tiredness, nausea, diarrhoea, constipation, or sudden shortness of breath. Serious side-effects include fever, chills, sudden shortness of breath, dry cough and tiredness which may be signs of infection; bleeding, or bruising more than normal.

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](http://www.tga.gov.au/reporting-problems).

## INQOVI® 35/100

**Active ingredient(s):** *decitabine and cedazuridine*

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### Consumer Medicine Information (CMI)

This leaflet provides important information about using INQOVI 35/100. **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 INQOVI 35/100.**

**Where to find information in this leaflet:**

- [1. Why am I using INQOVI 35/100?](#)
- [2. What should I know before I use INQOVI 35/100?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use INQOVI 35/100?](#)
- [5. What should I know while using INQOVI 35/100?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I using INQOVI 35/100?**

**INQOVI 35/100 contains the active ingredients decitabine and cedazuridine. INQOVI 35/100 is an anti-cancer medicine and it works by preventing the growth of cancer cells.**

**INQOVI 35/100 is used to treat myelodysplastic syndrome (MDS) or chronic myelomonocytic leukaemia (CMML). These are types of blood cancers in which the bone marrow does not work properly to produce mature blood cells. This causes a lack of healthy blood cells in the body.**

## **2. What should I know before I use INQOVI 35/100?**

### **Warnings**

#### **Do not use INQOVI 35/100 if:**

- you are allergic to decitabine or cedazuridine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are pregnant

#### **Check with your doctor if you:**

- have any other medical conditions such as severe heart, lung, liver or kidney problems

- take any medicines for any other condition.

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**

**Do not take this medicine if you are pregnant. It may affect your developing baby if you take it during pregnancy.**

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.

## **Women and men of childbearing potential**

Women must avoid becoming pregnant while taking INQOVI 35/100 but if you do become pregnant, tell your doctor immediately. Use an effective method of contraception during treatment with this medicine and for up to 6 months after taking your last dose.

Men must avoid fathering a child while taking INQOVI 35/100. Use barrier methods of contraception (e.g. condoms) during treatment with this medicine and for up to 3 months after taking your last dose if your partner is of childbearing potential. Talk to your doctor if you wish to conserve your sperm before having this treatment.

## Children

Do not give this medicine to a child under the age of 18 years. Safety and effectiveness in children has not been established.

### 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect INQOVI 35/100**

### 4. How do I use INQOVI 35/100?

#### How much to take

- The usual dose for this medicine is 1 tablet daily at the same time each day on the first 5 days of each 28 day treatment cycle.
- Your doctor may prescribe a different course or length of treatment depending on your blood counts.
- Follow the instructions provided and use INQOVI 35/100 until your doctor tells you to stop. The medicine is usually taken for at least 4 cycles or longer depending on your response.

## **When to take INQOVI 35/100**

- INQOVI 35/100 should be taken on an empty stomach, for example in the morning before eating. Do not consume food for at least 2 hours before and 2 hours after taking INQOVI 35/100.
- Food can interfere with the absorption of this medicine.
- If you miss a dose of INQOVI, take your dose as soon as possible if it is within 12 hours of your usual time. Then, continue taking INQOVI at your scheduled time. If you missed a dose by more than 12 hours, do not take additional doses to make up for the missed dose. Take your next scheduled dose on the following day at your usual time.

## **If you vomit after taking INQOVI 35/100**

If you vomit after taking the dose, do not take an additional dose. Take the next dose the next day as scheduled.

Talk to your doctor as he or she may give you a medicine to stop you from feeling sick.

## **If you forget to take INQOVI 35/100**

INQOVI 35/100 should be used regularly at the same time each day.

If you miss your dose and it is within 8 hours of your usual time, take your dose as soon as you remember, and continue to take it as you would normally.

**If it is over 8 hours of your usual time or almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

## **If you use too much INQOVI 35/100**

If you think that you have used too much INQOVI 35/100, you may need urgent medical attention.

**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 using INQOVI 35/100?**

### **Things you should do**

**Call your doctor straight away if you:**

- feel very unwell and have fever, severe chills, sore throat or mouth ulcers

- have signs of bleeding (e.g. nose bleeds) or bruising more easily than normal or if you are feeling more tired than usual
- if you become pregnant while taking this medicine.

Keep all your doctor's appointments so that your progress can be checked. Your doctor will do some tests e.g. blood tests, at regular intervals to make sure the medicine is working and to prevent any unwanted side effects.

Remind any doctor, dentist or pharmacist you visit that you are using INQOVI 35/100.

## **Things you should not do**

- Do not stop using this medicine without talking to your doctor
- Do not give your medicine to anyone else, even if they have the same condition as you.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how INQOVI 35/100 affects you.**

INQOVI 35/100 may cause fatigue and dizziness in some people.

## **Looking after your medicine**

Store below 25°C.

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.**

## **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**

<b>Less serious side effects</b>	<b>What to do</b>
<b>Gastrointestinal related:</b> <ul style="list-style-type: none"><li>• constipation or diarrhoea</li><li>• nausea and vomiting</li></ul> <b>Pain related:</b>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● muscle aches</li> <li>● headaches</li> <li>● back pain</li> <li>● painful, swollen joints</li> <li>● swelling of the ankles, feet or legs</li> </ul> <p><b>General well-being related:</b></p> <ul style="list-style-type: none"> <li>● tiredness or weakness</li> <li>● being short of breath when exercising, dizziness and looking pale</li> <li>● trouble sleeping</li> <li>● weight loss or decreased appetite</li> <li>● feeling unsteady on feet or falling over.</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>● swelling of the face, lips, tongue or other parts of the body</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● rash, itching or hives on the skin</li> </ul> <p><b>Infection related:</b></p> <ul style="list-style-type: none"> <li>● fever and severe chills</li> <li>● sore throat or mouth ulcers</li> <li>● sudden shortness of breath, dry cough, phlegm and occasionally blood</li> <li>● tiredness</li> <li>● swelling of the arms, legs, and neck</li> <li>● hot, tender and red skin</li> </ul> <p><b>Bleeding related:</b></p> <ul style="list-style-type: none"> <li>● bleeding or bruising more easily than normal</li> </ul>	<p><b>notice any of these serious side effects.</b></p>

Some of side effects such as changes in liver enzymes, blood levels of electrolytes and creatinine can only be found when your doctor does tests to check your progress.

**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](http://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 INQOVI 35/100 contains

<b>Active ingredient (main ingredient)</b>	Each tablet contains 35 mg of decitabine and 100 mg of cedazuridine.
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Lactose monohydrate</li><li>• Hypromellose</li><li>• Croscarmellose sodium</li><li>• Colloidal anhydrous silica</li><li>• Magnesium stearate.</li></ul>

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|  | <ul style="list-style-type: none"><li>• The tablet film-coating contains OPADRY II complete film coating system 85F15458 RED (PI 110931)</li></ul> |
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**Do not take this medicine if you are allergic to any of these ingredients.**

### **What INQOVI 35/100 looks like**

INQOVI 35/100 are biconvex, oval shaped, red film-coated tablets which are plain on one side and are marked with “H35” on the other side.

(AUST R 328904, 375556)

### **Who distributes INQOVI 35/100**

Otsuka Australia Pharmaceutical Pty Ltd

Suite 2.03, Level 2

9 Help Street

Chatswood NSW 2067

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