

Patient:

Date:

Off-label medicines

What are off-label medicines?

Before a company can sell a medicine in Australia the Therapeutic Goods Administration (TGA) needs to approve its use. The TGA is an Australian government body that checks:

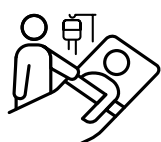
- how well a company makes the medicine (**quality**)
- how safe a medicine is (**safety**)
- how well it works to treat an illness (**efficacy**).

If approved, the TGA will list **how** and **when** healthcare teams can use the medicine.

Some illnesses may need treatment with medicines outside their TGA-approved uses. We call this an **off-label medicine**. Your doctor may offer an off-label medicine to treat your illness when an approved medicine:

- is not available
- caused you side effects, or
- was not right for you.

Using a medicine off-label can happen when the TGA approval does not list:



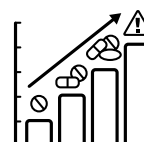
your illness



a form of the medicine suitable for you



your age group, sex etc.



the amount of medicine you need to treat your illness

It is important to know that an off-label medicine is **not bad**. But we often know less about how it works, or its safety for some people. Off-label medicine use is common in groups such as children or people at the end of life. For some off-label medicines:

- a hospital may approve its use within certain rules or for a research trial.
- other countries have approved the medicine but Australia has not.

Is an off-label medicine the right choice for you?



Your healthcare team will look at your medical history and evidence from studies to find out:

- how well an off-label medicine may help you (**benefits**)
- the possible side effects (**risks**).

Your doctor will talk with you or your carer about the benefits and risks of the off-label medicine. You are in charge of your health care. So, it is up to you if you want to try an off-label medicine or not.

To help you make this decision, here are some questions you or your carer can ask your doctor:

- How will this medicine help?
- Why do you think the benefits are worth the risk?
- Is there evidence that it will help people like me?
- What are the side effects and how likely are they?
- What other choices do I have?
- Can I use an approved medicine instead?
- What happens if I do not use this medicine?
- What are the costs?
- Can I join a research trial for this medicine?

These questions can help you make an informed decision. Take time to think about your choices and talk them over with your healthcare team.



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Consent



If using an off-label medicine is not a standard treatment, you may need to sign a consent form. This shows that you understand the benefits and risks of the medicine. The hospital will keep the signed form in your records.

You or your carer can decide to stop using the medicine at any time.

If you want to stop, talk to your doctor first in case you need to stop the medicine slowly.

What happens next?

In hospital, there may be an approval process before you can use the off-label medicine. A group of experts checks the evidence to show the medicine works and is safe. Your healthcare team will talk with you about this process and the next steps.

Your team may consist of doctors, nurses, pharmacists and other health professionals (e.g. Aboriginal and Torres Strait Islander Health Workers/Practitioners).

If the hospital approves the off-label medicine for you, a team member will talk with you or your carer about:

- how and when to get the medicine
- how to take or give the medicine
- how you will know if the medicine is working
- side effects and who to tell if they happen
- if you need any tests (e.g. blood tests and scans) and how often you need them.

Your team will track and record how your medicine is working and if you should keep using it. This may help decide if others should also use it in the future.

Over time your team may find out more about your off-label medicine. Your team may set up future checks to see if the off-label medicine is still the best choice for you.

Long-term use

If the hospital approves the off-label medicine, their pharmacy will supply it. If you need the medicine for a long time, please talk to your team about:

- who will prescribe the off-label medicine (your specialist or your family doctor)
- where to get the medicine (from the hospital or your local pharmacy)
- what you or your carer should tell other healthcare professionals about the medicine.

Where to get more information



Your team may give you a document with more information about your off-label medicine. This will include details about your medicine but may not be directly about your illness. Be aware: if you look up your medicine on the internet, the information may not be relevant for Australia and so **may not be correct**.

Talk to a member of your healthcare team or a patient advocate for more advice.

My off-label medicine

Medicine:	<input type="text"/>	This medicine will treat: <i>(add patient's illness)</i>	<input type="text"/>
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If you have any questions, please call:

Name:	<input type="text"/>	Telephone:	<input type="text"/>
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CATAG presents the information in this document with all due care. CATAG accepts no responsibility for any loss, claim or damage as a result of using this information. This information does not replace medical advice.

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