

Medicines for epilepsy, mental health, and pain can harm your unborn baby

Talk to your doctor about the risks to you and your baby, and how to balance them



Remember, whatever happens, keep taking your medicines until you've talked to your doctor

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This information is intended to provide guidelines and general advice to healthcare professionals, but should not be used as a substitute for assessment with the circumstances that are relevant to the individual patient.



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Medicines for epilepsy, mental health, and pain can harm your unborn baby

Some medicines for epilepsy, mental health problems (like bipolar disorder), and chronic pain (long term pain that is difficult to manage with painkillers like paracetamol), can harm an unborn baby. We've listed the medicines on pages 9-10, and statistics on the risks on pages 12-13.

If you could get pregnant – or are going to start having periods soon, you should talk to your doctor about the medicines you're taking. And if you do get pregnant, talk to your doctor as soon as you can.

This booklet is for anyone who could get pregnant and their family and whānau.

This booklet is for everyone who could get pregnant and is taking medicines for epilepsy, mental health problems (like bipolar disorder), or pain.

This booklet will help you, your family, and your whānau understand:

- the benefits and risks of taking these medicines, and how to talk to your doctor about balancing the risks – even if you're not planning to get pregnant
- when to make a pregnancy plan with your doctor if you're thinking about having a baby
- why you must keep taking your medicines until you've talked to your doctor.

Talk to your doctor to understand the balance of risks

It's hard to accurately predict the risks of taking these medicines. The risks you face will depend on the medicine you take, how much you take (the dose), and whether you are taking more than one medicine (what doctors call polytherapy).

Taking these medicines when you're pregnant has two main risks:

1. An unborn baby may not form as it should (it may have malformations). Malformations may include a cleft palate (a split in the roof of the mouth), heart defects, or spina bifida (a birth defect that can mean serious physical and mental disabilities).
2. Children may have learning problems or autism.

We've done our best to use gender-neutral language

This booklet is for everyone who's taking the medicines and could get pregnant, no matter how they identify. We want to reach women, transgender people, and non-binary people.

We've used language that's gender inclusive, except where job titles and services have gender-specific terms included, e.g. lead maternity carer.

Four important actions you can take

1. Keep taking your medicines until you've talked to your doctor

Your medicines help you stay well and live well. If you suddenly stop taking them, or reduce how much you take (the dose), you can put yourself – and an unborn baby – at risk.

2. Talk to your doctor

Your doctor will explain what you can do to avoid getting pregnant by accident, and how to reduce the risks to your unborn baby if you do get pregnant.

You should talk to your doctor if you:

- are likely to start having periods soon
- are having periods and are sexually active
- are thinking about having a baby
- have taken these medicines while you were pregnant.

3. Use two kinds of contraception – your doctor will help you choose the right ones

If you could get pregnant– even if it seems unlikely – you should use two kinds of contraception. This means condoms plus another contraceptive, possibly an intra-uterine device (often called an IUD) or the Depo-Provera injection.

But talk to your doctor before you choose a second kind of contraception – some don't work with some medicines.

4. Take 5mg of folic acid every day when planning a pregnancy and in the first 12 weeks

Folic acid helps babies develop healthily in early pregnancy. Taking 5mg of folic acid every day helps reduce the risks to your unborn baby.

Your checklist

What to do if you take these medicines and could get pregnant

	Keep taking your medicines	Talk to your doctor	Use two kinds of contraception	Take 5mg folic acid daily	Call your doctor now
If you could get pregnant	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	
If you're planning to get pregnant	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	
If you're pregnant, or think you could be pregnant	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
If you've had a baby while taking these medicines	<input checked="" type="radio"/>	<input checked="" type="radio"/>			
If you haven't started having periods	<input checked="" type="radio"/>	<input checked="" type="radio"/>			

What medicines are you taking?

The advice in this booklet applies to the medicines on this list. These medicines are used to treat epilepsy, mental health, and chronic pain in New Zealand.

Talk to your doctor if your medicine isn't on this list

Brand names change and new medicines become available.

The risks can be different for each person

We know that some of these medicines can harm the development of unborn babies - sodium valproate (Epilim®) is most likely to – but predicting the risks is complex.

The risks you face will depend on the medicine you take, how much you take (the dose), and whether you're taking more than one medicine (what doctors call polytherapy).

Talk to your doctor to understand the balance of risks

Your doctor can help you understand the risks and benefits of the medicines you take – these medicines help many people stay well and live well.

Your doctor will help you decide how best to balance the risks for you and your unborn baby.

List of medicines

Brand name	Scientific name
Apo-Primidone [®]	Primidone
Arrow-Gabapentin [®]	Gabapentin
Arrow-Lamotrigine [®]	Lamotrigine
Ativan [®]	Lorazepam
DBL [®]	Diazepam
Dilantin Infatabs [®]	Phenytoin
Epilim [®]	Sodium valproate
Everet [®]	Levetiracetam
Frisium [®]	Clobazam
Inovelon [®]	Rufinamide
Keppra [®]	Levetiracetam
Lamictal [®]	Lamotrigine
Levetiracetam AFT [®]	Levetiracetam
Logem [®]	Lamotrigine
Lyrica [®]	Pregabalin
Mogine [®]	Lamotrigine
Motrig [®]	Lamotrigine
Neurontin [®]	Gabapentin

List of medicines continued

Brand name	Scientific name
Paxam [®]	Clonazepam
Phenobarbitone PSM [®]	Phenobarbital
Rivotril [®]	Clonazepam
Sabril [®]	Vigabatrin
Sativex [®]	Medicinal cannabis
Tegretol [®]	Carbamazepine
Topamax [®]	Topiramate
Topiramate Actavis [®]	Topiramate
Trileptal [®]	Oxcarbazepine
Trobalt [®]	Retigabine
Vimpat [®]	Lacosamide
Zarontin [®]	Ethosuximide



The risks to your unborn baby

Taking medicines for epilepsy, mental health, or pain when you're pregnant has two main risks:

- An unborn baby may not form as it should (it may have malformations). Malformations may include a cleft palate (a split in the roof of the mouth), heart defects, or spina bifida (a birth defect that can mean serious physical and mental disabilities).
- Children may have learning problems or autism.

The risks can be different for each person

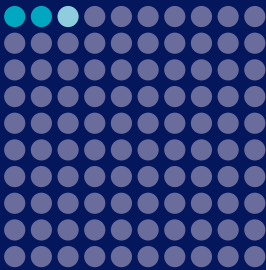
We know that some of these medicines can harm the development of unborn babies – sodium valproate (Epilim®) is most likely to – but predicting the risks is complex.

The risks you face will depend on the medicine you take, how much you take (the dose), and whether you're taking more than one medicine (what doctors call polytherapy).

Understanding the risks

Children with malformations

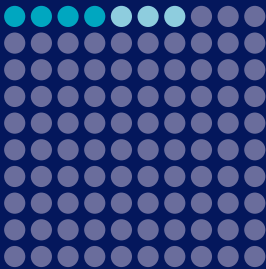
Malformations include spina bifida, cleft palate, and heart defects.



2 to 3
out of 100 babies

not exposed to these medicines will have these problems.

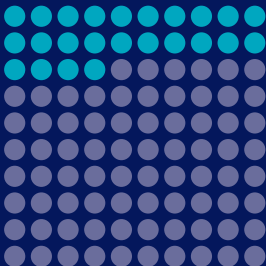
This is a low risk.



4 to 7
out of 100 babies

exposed to these medicines of any dose will have these problems.

This is a high risk.

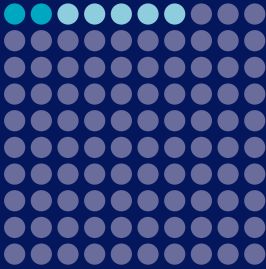


24
out of 100 babies

exposed to more than 1500mg of sodium valproate (Epilim®) will have these problems.

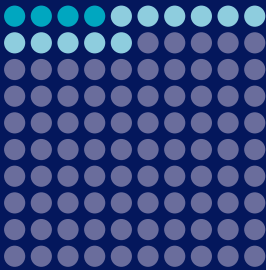
This is a very high risk.

Children with learning problems or autism



Between **2 and 7**
out of 100 babies

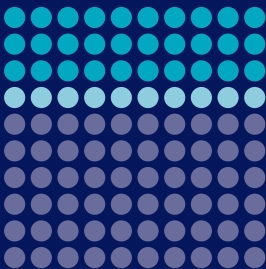
that aren't exposed to these
medicines will have autism.
This is a low risk.



Between **4 and 15**
out of 100 babies

exposed to more than 800mg of
sodium valproate (Epilim®) per day will
have autism. **This is a medium risk.**

**Babies exposed to sodium valproate
(Epilim®) may have learning
problems and a decreased IQ.**



Between **30 and 40**
out of 100 babies

exposed to more than 800mg of
sodium valproate (Epilim®) per day
will have developmental delays.

This is a very high risk.

**These children are 8X
more likely to need extra help at
school than the other children.**

If you could get pregnant

If you could get pregnant, you have what healthcare professionals call 'childbearing potential'.

Take extra care with contraceptives

Medicines for epilepsy, mental health, or chronic pain can harm an unborn baby before you know you're pregnant (see page 11 'The risks to your unborn baby').

So you should take extra care with contraceptives if you have childbearing potential. Taking extra care will minimise the risk of getting pregnant by accident.

Talk to your doctor, and check in once a year

Make an appointment with your doctor to decide what's right for you, and take this booklet with you. Your doctor will want to talk to you about these three things (at least):

- **Use two types of contraceptive.** Some kinds of contraception don't work properly if you're taking some medicines. So your doctor will suggest you use two kinds of contraception. For example, this could mean condoms plus another contraceptive, possibly an intra-uterine device (often called an IUD) or the Depo-Provera injection.
- **Taking 5mg of folic acid every day.** Folic acid helps babies develop healthily in early pregnancy. So taking 5mg of folic acid every day will help reduce the risks to your unborn baby. Ideally you should start taking folic acid 12 weeks before you get pregnant, and continue for the first 12 weeks of pregnancy. Over the counter pregnancy vitamins contain a low dose of folic acid so ask your pharmacist, doctor, or midwife for a 5mg dose.
- **Checking in on your medicines once a year.** Your symptoms may change over time, and new medicines may come out. Meet with your doctor once a year so they can prescribe the medicines that are right for you.

See page 25 'Your doctor will help you make the best decisions for you and your baby'.

**If you think you might be pregnant,
talk to your doctor immediately.**

If you're planning to get pregnant

The medicines you're taking can harm an unborn baby. Your doctor will help you draw up a pregnancy plan that will aim to keep you and your baby well.

Remember to keep on taking your medicines until you have a pregnancy plan. If you stop taking your medicines, or reduce how much you take (the dose), you can put yourself and your unborn baby at risk.

Put together a pregnancy plan before you try for a baby

Talk to your doctor as soon as you start thinking about having a baby. Your doctor will help you look at the risks and benefits of taking the medicines. So the plan may say you should keep taking the medicines, even though there are risks.

See page 24 'Your doctor will help you make the best decisions for you and your baby'.

Plan your pregnancy at least six months – ideally a year – ahead

You'll need time to adjust to any new medicines or dosages, and to make sure you've done all you can to reduce the risks to you and your baby. You should talk to your doctor 6-12 months before you start trying for a baby.

Your pregnancy plan will include advice on:

- using two kinds of contraception (such as condoms plus another kind) while you're planning your pregnancy
- managing your medicines and the dose
- taking 5mg of folic acid every day, starting 12 weeks before you start trying to get pregnant, and continuing for the first 12 weeks of your pregnancy.

Your pregnancy plan will help you balance the risks

Your doctor will talk to you about how to balance the risks and benefits of your medicines.

Your doctor will want to talk to you about:

- the medicines you're taking, and why you take them
- changes to your medicines that will reduce risks, like a lower dose or a different medicine
- other ways to reduce risks, like taking 5mg of folic acid every day and making changes to your lifestyle.

Find out more about how to get ready for a conversation with your doctor – see page 24.

If you're pregnant, or think you could be pregnant



The medicines you're taking can harm an unborn baby before you know you're pregnant. But remember that these risks don't happen to everyone, so it is important to keep taking your medicines even if you think you are pregnant.

Get an urgent medical appointment if you're pregnant, or think you might be

You should get an appointment with your doctor as soon as you can. Your doctor will do their best to help you manage your condition and minimise the risks to you and your baby.

You should also tell your pharmacist that you're pregnant, or could be pregnant.

Keep on taking your medicines until you speak to your doctor

Your medicines help you stay well and live well. If you suddenly stop taking them, or reduce how much you take (the dose), you can put yourself – and your unborn baby – at risk.

Take 5mg of folic acid every day

Folic acid helps babies develop healthily in early pregnancy. Taking 5mg of folic acid every day when planning a pregnancy and for the first 12 weeks of pregnancy helps reduce the risks to your unborn baby.

Your doctor or midwife may give you a prescription for the folic acid, so you won't have to pay the full price.

**If you think you might be pregnant,
talk to your doctor immediately.**

If you've had a baby while taking these medicines

Talk to your child's doctor or paediatrician if you think your child has been affected by your medicines. They may refer you to a specialist.

Gather the details the specialist is likely to need

The specialist will ask you a lot of questions. It's a good idea to make sure you have the information they'll need. This includes:

- a list of the medicines you were taking when you were pregnant
- a copy of your medical records – these can take a few weeks to get, so make sure you ask for them in advance.

See 'Find out more' on page 28 to find out how to get a copy of your medical records.

List your questions ahead of the appointment, and decide if you want a support person with you

Write down the questions you want to ask ahead of your appointment. The Let's PLAN web pages have information that will help you prepare for your appointment (safer.nz/HQSC-LetsPlan).

You might want to take your partner or a support person to the appointment. Many people find it useful to have someone else there to take notes of what you and the specialist talk about.

Remember that you may not get quick answers, as the specialist may refer your child for tests.

Check whether you can get support from ACC

If your child has been affected by these medicines, you may be eligible for support from ACC. Talk to your doctor about whether you should lodge a Treatment Injury claim.

Find out more about support organisations – see page 28.

If you haven't started having periods



If you're taking any of the medicines, but haven't started having periods, you should talk to your doctor.

You can see your doctor on your own

Remember that you can see a doctor without a parent or guardian, even if you're under 16.

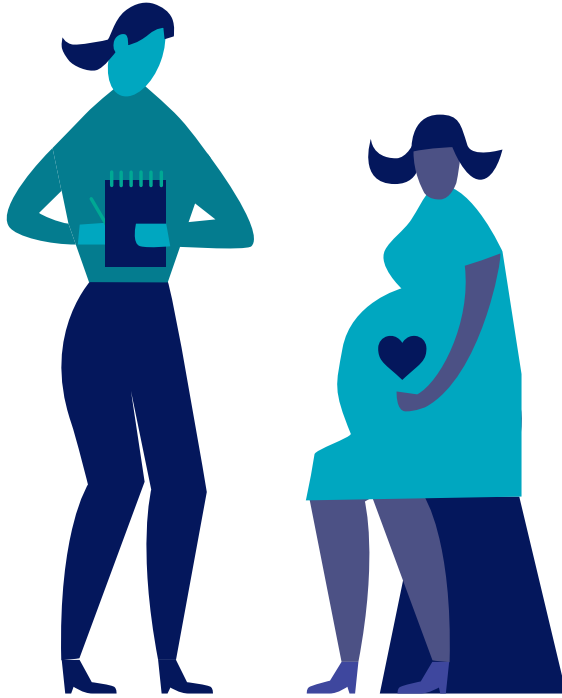
Your doctor can't tell anyone about what you talked about, unless they think you're at risk of harm.

Get advice on the medicines and contraceptives that are best for you

Your doctor will talk to you about what you need to think about as you get older or start having sex. Because the medicines you take can harm an unborn baby, you'll have to take extra care not to get pregnant without planning to.

Your doctor will usually talk to you about:

- whether you need to change your medicines as you start your periods
- using two kinds of contraception – such as condoms plus another contraceptive, like an intra-uterine device (often called an IUD) or the Depo-Provera injection.



**Your doctor will help you
make the best decisions
for you and your baby**

Your doctor will help you understand the benefits and risks of taking medicines for epilepsy, mental health, or pain. At an appointment, you can talk about what you can do to reduce the risks.

Your doctor will help you make informed choices, and make the best decisions for you and your baby.

How to plan your appointment with your doctor

Before you see your doctor, prepare yourself by thinking about who you want to go with and what you want to ask.

Decide who to take with you

You might want to take your partner or a support person to the appointment. Many people find it useful to have someone there to take notes on what you and the doctor talk about.

Make a list of the questions you want to ask your doctor

Make sure you ask your doctor the following questions:

- What else can I do, including taking other medicines, to reduce the risk of harm to my baby and me?
- Who will be my lead health professional, the person who organises my care? It's usually your doctor or a midwife.
- Who will coordinate my pregnancy care, and any referrals to specialist maternity services?
- Who will you refer me to for pregnancy care?
- Will you make sure that my lead maternity carer (e.g. midwife or specialist doctor) is included in any correspondence?

What to expect at your appointment

This appointment may take longer than usual. You and your doctor need to make a plan to keep you as healthy as possible while you're pregnant, and reduce the risk of harm to your baby.



You may find it useful to start a notebook – there'll be a lot to remember

Take your time and make sure you get all the answers you need. You might want to write things down in a notebook or take notes on your phone or tablet.

Make sure you give all your healthcare professionals the same information, and tell them who else you've seen.

Remember that you have the right to see your medical records, and you can ask to be sent copies of healthcare professionals' letters and emails about your care.

'ACC's Know What to Ask' booklet is a helpful resource to use to prepare for your appointment.



www.acc.co.nz/assets/provider/b7dd454892/get-most-out-of-healthcare.pdf

Go back to your doctor if you need to

If you think of other questions after the appointment, or you aren't sure about something, contact your doctor again.

That's OK – you have the right to understand the risks and how to balance them.

Read advice from The Health Quality & Safety Commission on how to plan for appointments

These 'Let's PLAN for better care' web pages will help you plan your appointment:




safer.nz/HQSC-LetsPlan

Find out more

Where to get more information on health and medicines

Health Navigator NZ is a widely respected website that aims to help ordinary New Zealanders ‘navigate the health information maze’.

 www.healthnavigator.org.nz

My Medicines is run by a team at Canterbury District Health Board. The website provides plain language information about medicines used in New Zealand – in English and te reo Māori.

 www.mymedicines.nz/cdhub

How to get a copy of your medical records

Speak to your health care provider. This may take a few weeks so make sure you ask ahead of time.

Support services for people living with epilepsy and mental health problems

Epilepsy Association of New Zealand

www.epilepsy.org.nz

0800 374 537

national@epilepsy.org.nz

Foetal Anti-Convulsant Syndrome NZ (FACS NZ)

www.facsnz.com

021 189 4483

denise@facsnz.com

Mental Health Foundation

www.mentalhealth.org.nz

09 623 4810

info@mentalhealth.org.nz

How to report a side effect of a medicine

If you've suffered side effects when you've taken medicine, you can report it to the Centre for Adverse Reactions Monitoring (CARM).

<https://nzphvc.otago.ac.nz/consumer-reporting>

03 479 7247

carmnz@otago.ac.nz

How to order printed copies of this booklet

To order printed copies of this booklet please email treatmentsafety@acc.co.nz





Te Kaporeihana Awhina Hunga Whara



MANATŪ HAUORA



Foetal Anti-Convulsant Syndrome New Zealand



HEALTH QUALITY & SAFETY
COMMISSION NEW ZEALAND

Kupu Taurangi Hauora o Aotearoa