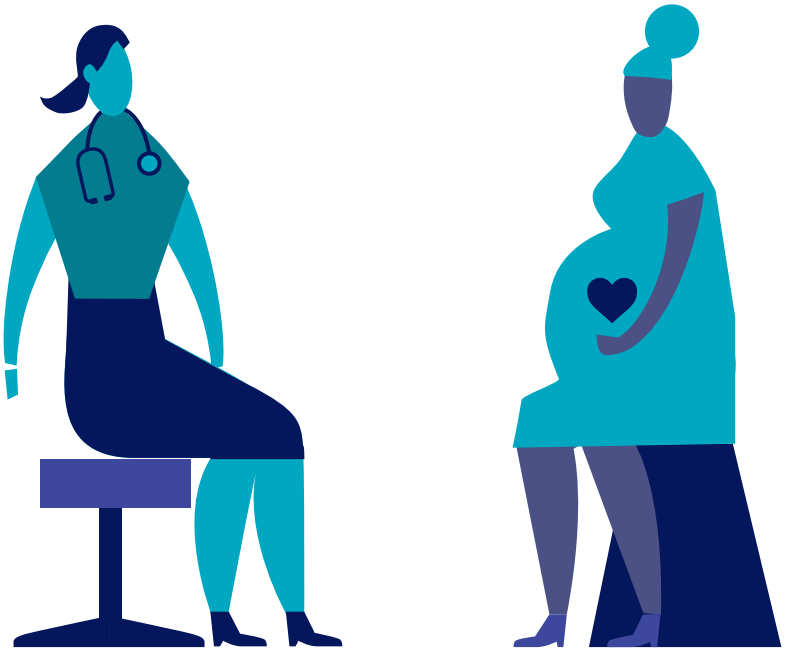
Have the conversation:

Benefits and risks of taking anti-seizure medicines for epilepsy, mental health, or pain

Information for healthcare professionals to discuss with anyone who could get pregnant



Benefits and risks of taking anti-seizure medicines for epilepsy, mental health, or pain

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ACC7809 May 2020

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.

Contents

Who is this booklet for?

This booklet is aimed at those who provide healthcare to anyone who could get pregnant[1] who is taking anti-seizure medicines for epilepsies, mental health, or pain.

This booklet was reviewed and updated by a panel of experts in general practice, midwifery, obstetrics, psychiatry, neurology, pharmacy and health quality and safety, and representatives of consumer groups for epilepsy and mental health.

Helping consumers to make informed decisions

It is clearly established that anti-seizure/mood stabilising medicines are associated with congenital malformations (such as spina bifida, cleft palate, and heart defects), and cognitive impairment and behavioural difficulties (such as Autism Spectrum Disorder). **Some medicines, particularly sodium valproate, carry very high risks that are dose-dependent.**

When a child has dysmorphic features combined with other malformations some people use the term 'Fetal Anticonvulsant Syndrome'.

While the dose or type of anti-seizure/mood stabilising medicine can't always be altered, clear information is still very important to help people make an informed decision.

[1]This information is important for anyone considering pregnancy, no matter how they identify their gender, including trans men and non-binary people who are thinking of getting pregnant or who are pregnant. Most terms have been made as gender-inclusive as possible, however some terms such as maternity may be included. Where job and service titles include this word it is difficult to provide a neutral term.

This booklet provides information for you, as a healthcare professional, to:

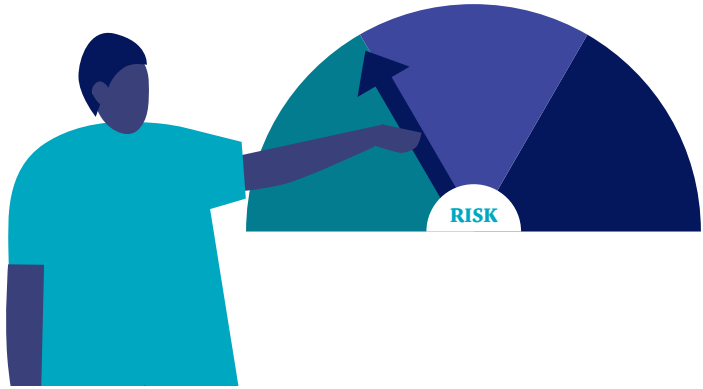
- understand and quantify the risk of harm to a fetus from medicines traditionally used to treat epilepsies, when taken for any indication
- educate consumers about those risks if they are considering or already taking these medicines and might become pregnant
- support consumers to optimise their use of these medicines
- discuss contraception and prescribe two effective methods that are compatible with specific anti-seizure/mood stabilising medicines, for those who do not wish to become pregnant.

Information booklet for healthcare consumers

Alongside this booklet, you should read the information booklet for healthcare consumers 'Medicines for epilepsy, mental health and pain could harm your unborn baby. Talk to your doctor about the risks – to you and your baby – and how to balance them'.

You should make sure that the consumer has a copy of the consumer booklet, and take the time to talk it through with them.

Key messages



Balancing the risks

- Make sure that consumers of these medicines are aware of the balance of risk associated with taking them while pregnant, and the risk if the medicines are not taken as prescribed.
- All anti-seizure/mood stabilising medicines taken in pregnancy have the potential to harm a fetus, regardless of the condition being treated.
- **Sodium valproate has the highest risk of harm. Do not prescribe sodium valproate to anyone of childbearing potential without careful consideration and input from specialists, and unless there is no reasonable alternative.**

Advice for consumers

- Advise consumers to use **TWO** effective forms of contraception. Some contraceptives interact with enzyme-inducing anti-seizure/mood stabilising medicines (see table on p.21).
- Advise consumers to plan their pregnancy in consultation with a doctor or specialist, as many pregnancies are unplanned.[14]
- If a consumer gets pregnant by accident, tell them to keep taking their medicines and that you'll get urgent specialist advice.
- Advise consumers to take a high dose (5mg daily) of folic acid, for 12 weeks before trying to get pregnant and for 12 weeks after conception.[5]

Key actions you should take

- Each year, review the anti-seizure or mood stabilising medicines a consumer is taking. Check the appropriateness of their medicines, and reinforce relevant messaging. Consider referral to a specialist to ensure the medicine and dose is still optimal for the consumer.
- Fully document your discussion and evidence of informed decision making processes in the clinical notes, including what booklets were given.[1]

Pathway for your conversation with consumers

Identify consumer of childbearing potential who needs or is taking anti-seizure or mood stabilising medicines

Explore all alternatives to sodium valproate or polytherapy

If these medicines are unavoidable

If the consumer is **not** planning pregnancy:

- **review their medicines annually**
- **ensure they are using two forms of contraception**
- **ensure they understand the importance of planning pregnancy 6-12 months in advance.**

If the consumer **is planning** pregnancy:

- **make a plan with them 6-12 months in advance**
- **consider options to change, reduce, or stop medicine**
- **ensure they are using two forms of contraception until ready to get pregnant**
- **prescribe 5mg of folic acid daily, for at least 12 weeks before conception and 12 weeks after.**

If the consumer **is pregnant**:

- **seek specialist advice immediately**
- **explain the balance of risks**
- **discuss options to change, reduce, or stop medicine**
- **prescribe 5mg of folic acid daily, for 12 weeks after conception.**

Provide the consumer with a copy of the booklet **'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',** and talk this through with them

We have produced the booklet 'Medicines for epilepsy, mental health, and pain could harm your unborn baby. Talk to your doctor about the risks – to you and your baby – and how to balance them', to help you go through these risks with people using these medicines who might become pregnant.

Please provide them with an electronic copy, or a copy to take home with them.

Balancing the risks

The specific risk from anti-seizure/mood stabilising medicines can only be reduced by decreasing the dose or changing the medicine.

However, any reduction in risk to the fetus must be discussed with the consumer and balanced against the risk for the parent of changing the dose or medicine.

Changes to the dose or medicine type should be considered before pregnancy.

The risks of changing medicine for anyone with an epilepsy may be significant

- Decreasing or changing the anti-seizure medicine may cause loss of seizure control.
- There is a risk of status epilepticus if the anti-seizure medicine is weaned quickly.
- Seizures themselves can have a negative effect on a fetus, including hypoxia or miscarriage.
- A consumer who can't control their seizures faces a higher risk of sudden death. Epilepsy is associated with Sudden Unexplained Death in Epilepsy (SUDEP) in 1 in 1,000 pregnancies.[5] The only way to decrease this risk is to control seizures.
- The risk of maternal death due to status epilepticus is 10 times greater in pregnancy. The medication dose should be managed closely by a specialist, particularly towards the end of pregnancy, when it may need to be increased.

It is important that any changes to the anti-seizure medicine for someone with an epilepsy are made in consultation with a neurologist or paediatrician.

There are risks to the consumer if bipolar disorder is not adequately treated

While there are risks to the fetus of taking mood stabilising medicines during pregnancy, the risks of inadequate treatment for bipolar disorder are significant.[12] These include:

- In the extreme, untreated bipolar disorder can lead to serious relapse of illness and suicide.
- Pregnant people with bipolar disorder who stop taking their mood stabilising medicines are twice as likely to have a relapse of mood symptoms. This may be a relapse of depression or mania, both of which have an adverse effect on the parent's wellbeing.
- Depression and mania are also associated with poorer birth outcomes such as prematurity and small babies.
- The risk and speed of relapse increases significantly if medicines are stopped abruptly; tapering is safer. If the consumer becomes unwell, higher doses of medication may be needed.
- The risk of puerperal psychosis for people with untreated bipolar disorder rises from 0.1-0.25% (prevalence in the general population) to 50%. For 17%, this can be a severe illness, potentially requiring hospitalisation.

People with bipolar disorder have an increased risk of unplanned pregnancy, for various reasons, but including sexual disinhibition associated with mania.

The risks of taking anti-seizure medicines used to treat epilepsies, mental health, and pain during pregnancy

The risks vary depending on the medicine but fall into two main categories: congenital malformations and neurodevelopmental effects.

These medicines may also increase the risk of obstetric complications such as miscarriage, or intrauterine growth restriction (IUGR).

Sodium valproate and polytherapy carry the highest risk of congenital malformations

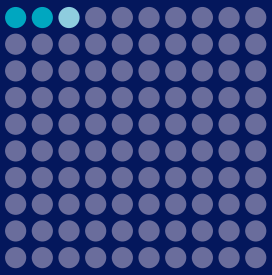
Sodium valproate carries a 10% risk of congenital malformation. This rises considerably at higher doses (24% with >1500mg/day). Phenobarbital, phenytoin, carbamazepine, and topiramate also carry high risk. Lower levels of risk are associated with lamotrigine and levetiracetam (see Figure 1[15]).

When more than one anti-seizure/mood stabilising medicine is used during pregnancy, the reported rate of congenital malformations was 17%.[5] Polytherapy that includes sodium valproate carries the highest overall risk.

The Epilepsy Pregnancy Registry sample sizes are generally too small to attribute particular types of malformations to specific anti-seizure medicine exposure, but there are case reports of malformations of most body systems.

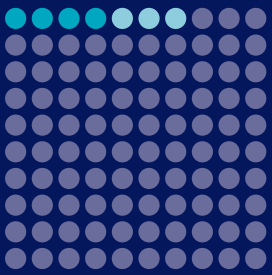
Understanding the risks

Risks of malformations such as spina bifida, cleft palate, and heart defects



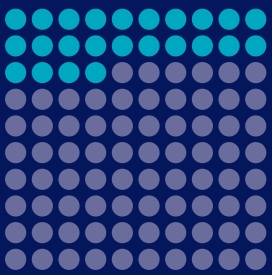
2 to 3
out of 100 babies

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.

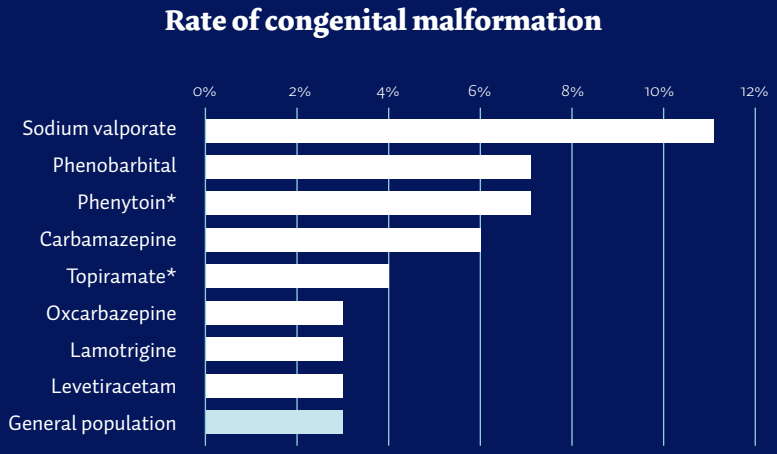


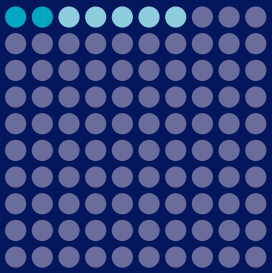
Figure 1: Rates of major congenital malformation associated with anti-seizure medicine use. N.B. this data does not include neurodevelopmental adverse effects in affected children.

* Data on risks associated with phenytoin or topiramate use are based on limited numbers of pregnancies.

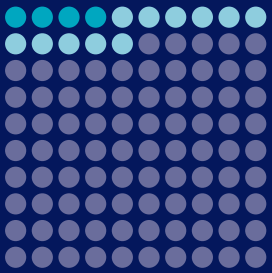
Sodium valproate and polytherapy carry a very high risk of neurodevelopmental effects

The risks of neurodevelopmental effects are shown on the next page. Less data is available on the neurodevelopmental effects of anti-seizure/mood stabilising medicines other than sodium valproate. However, where multiple anti-seizure/mood stabilising medicines are taken during pregnancy, there are reports of reduced intelligence and lower educational achievement in children.[5][7]

Risks of neurodevelopmental effects

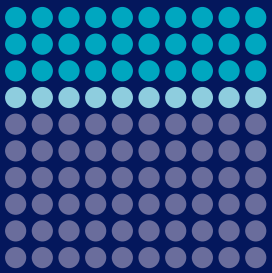


Between 2 and 7
out of 100 babies
that aren't exposed to these medicines will have autism.
This is a low risk.



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.

Sodium valproate should only be prescribed if no alternative is available

Mental health (including bipolar disorder), pain, and focal epilepsies

Do not initiate a new prescription for sodium valproate in a sexually active person of childbearing age for mental health, pain, or focal epilepsies unless all reasonable alternative medicines have been tried and have failed, or have not been tolerated. You should discuss the balance of risk with the consumer.

Consider other options before you prescribe sodium valproate at standard doses:

- consult a specialist who may be able to suggest other medicines[13]
- investigate whether non-medication strategies could be appropriate and sufficient, with support and regular monitoring
- only use the lowest effective dose, and as monotherapy.

Before initiation, a pregnancy test should be done, and the prescription should then be monitored by a specialist.

Generalised epilepsies

For generalised epilepsies, such as Juvenile Myoclonic Epilepsy, sodium valproate is known to be the most effective anti-seizure medicine. For some people, this may be the only medicine that is effective in controlling their seizures, and may need to be continued despite the risks in pregnancy.

Lamotrigine and levetiracetam are less effective, but can provide good seizure control for some people. They should be tried at a reasonable dose first. However, if control is not achieved, then sodium valproate may be necessary.

You should give the consumer information on the range of anti-seizure medicine options. This should include the medicine's likely effect on seizures and the risk for any future pregnancies. This will make sure they are well informed when choosing an anti-seizure medicine.

Remember to always check you have been understood at the end of any discussion.

It is important that the consumer has the information they need to make an informed decision

Anyone taking anti-seizure/ mood stabilising medicines who is not pregnant

Make sure the consumer is aware of the risks

If someone of childbearing potential is taking an anti-seizure/ mood stabilising medicine for any reason, consider:

- a reduction in dose, or
- a change to a medicine with lesser risk.

It is important that you include them in the decision making.

If the consumer is actively considering pregnancy or is at high risk of accidental pregnancy, this needs to be done urgently.

Every year, you must review the consumer's medicine, including:

- the appropriateness of their medicine
- reinforcing the importance of effective contraception and pregnancy planning
- providing advice on taking a high dose (5mg) of folic acid daily, in case of pregnancy.

Consumers should use two forms of contraception

If the consumer is, or could be, sexually active, you should advise and encourage them to use two forms of effective contraception. The dual method is important because enzyme-inducing anti-seizure/mood stabilising medicines can interact with hormonal contraception and make it less effective. Consider referral for expert contraceptive advice.

Table 1 indicates which contraceptives are recommended for use alongside condoms, taking into account the potential for the medicine's interactions with enzyme-inducing anti-seizure/mood stabilising medicines as in Table 2.

If you prescribe an oral contraceptive, make sure the consumer knows what to do if they miss a dose, or if vomiting or diarrhoea occurs.

The recommended emergency contraception depends on the type of medicine being taken

Standard emergency contraceptive options can be used for people taking non-enzyme inducing anti-seizure/mood stabilising medicines (Table 2).

A copper IUD or levonorgestrel (3mg/two tablets) are recommended for emergency contraception for people taking enzyme-inducing anti-seizure/mood stabilising medicines (see Table 2).

Table 1: Contraceptives recommended alongside condoms

This guide relates specifically to contraceptive/anti-seizure or mood stabilising medicine interactions. It does not take into consideration other factors that may influence contraceptive eligibility.

The choice of contraceptive might be influenced by the effect of the contraception on the medicine, or the medicine on the contraception.

Contraceptive method (use one recommended option plus condoms)	% of women experiencing pregnancy after one year of typical use	Anti-seizure medicine	
		Enzyme-inducing^, eg carbamazepine, phenytoin	Non-enzyme inducing^, eg sodium valproate, lamotrigine, levetiracetam
Intrauterine device - copper or levonorgestrel (e.g. Mirena/Jaydess)	<1%	✓	✓
Progesterone-only implant (e.g. Jadelle)	<1%	Not recommended*	✓
Medoxyprogesterone acetate injections	6%	✓	✓
Combined hormonal oral pill or vaginal ring	9%	Not recommended*	(except for lamotrigine)**
Progesterone-only pill^^	9%	Not recommended*	✓
Condom	18%	✓	✓
If emergency contraception is required		Copper IUD recommended Alternative: 3mg levonorgestrel (two tablets)	Standard emergency contraceptive options, ie 1.5mg levonorgestrel or copper IUD

* Not recommended due to a decrease in contraceptive efficacy
** Not recommended if taking lamotrigine due to a decrease in anti-seizure efficacy
^ See Table 2
^^ Subsidised progesterone only pills need to be taken within a three-hour window to ensure contraceptive effectiveness

Table 2: Anti-seizure medicines and their effects on hepatic enzymes

Enzyme-inducing anti-seizure medicines	Non-enzyme-inducing anti-seizure medicines
Carbamazepine	Clobazam
Oxcarbazepine	Clonazepam
Phenobarbital	Ethosuximide
Phenytoin	Gabapeztin
Primidone	Lacosamide
Rufinamide	Lamotrigine
Topiramate	Levetiracetam
	Pregabalin
	Retigabine
	Sodium valproate
	Vigabatrin

Anyone taking anti-seizure/ mood stabilising medicines who is planning a pregnancy

Pregnancy should be planned 6-12 months in advance

You should encourage a discussion of pregnancy plans at least 6-12 months in advance.

Folic acid should be taken for 12 weeks prior to conception, at the higher dose of 5mg per day. This should continue until 12 weeks into the pregnancy.

Folic acid reduces the risk of neural tube defects including spina bifida. However, it does not reduce other teratogenic effects of anti-seizure/mood stabilising medicines.

If a consumer gets pregnant without planning, refer them urgently to, or talk with, their neurologist or psychiatrist. Ideally this will happen within 48 hours of the pregnancy being confirmed. Also, refer the consumer to an obstetrician early.

Advise consumers to continue taking their medicines until they have seen a specialist as stopping may cause adverse effects.

Planning is especially important for people with epilepsy

This helps to manage the combined risks of pregnancy, epilepsy, and the anti-seizure medicines used to control seizures.

- Approximately one-third of people with epilepsy have an increased frequency of seizures during pregnancy.[5]
- Seizures during pregnancy carry risks for both the parent and fetus. Risks include pregnancy loss, pre-term birth, reduced birth weight, and changes in fetal heart rate. Uncontrolled seizures are also a risk factor for sudden unexpected death in epilepsy (SUDEP).

Planning means that:

- treatment can be altered as necessary to establish good seizure control
- a medicine regimen can be used that has the lowest possible risk of harm to the fetus
- seizure control during pregnancy can be improved
- fewer pregnancies are exposed to sodium valproate, and fewer changes to anti-seizure medicine are needed during pregnancy.[11]

You should make sure the consumer has an early referral to a lead maternity carer (LMC), and that their obstetric care is coordinated. Local referral processes and pathways should be followed.

Anyone taking anti-seizure/ mood stabilising medicines who is pregnant

The risks of major congenital effects from taking anti-seizure/ mood stabilising medicines occur mainly in the first trimester. The opportunity to reduce these risks is limited if the pregnancy is identified later.

However, the effects of sodium valproate on the child's cognition may occur at any time in the pregnancy, so there is some potential to reduce the risks even if pregnancy has already begun.

In people with an epilepsy, do not make a change to their anti-seizure medicine or withdraw it without discussion with a specialist, as this carries substantial risk for the parent and fetus.

In people using the medicine for mood stabilisation or pain, seek advice.

Consult with the appropriate specialist within 48 hours. This will usually be a neurologist, psychiatrist or possibly paediatrician. Refer for early consultation with an obstetrician as well.

Due to the risks involved, all members of the healthcare team need to communicate clearly with each other. All information needs to be shared between primary care (including the LMC), and the specialty services.

Anyone taking anti-seizure/ mood stabilising medicines who has not yet reached menarche, or is not sexually active

It is important that the individual receives the right treatment for their condition.

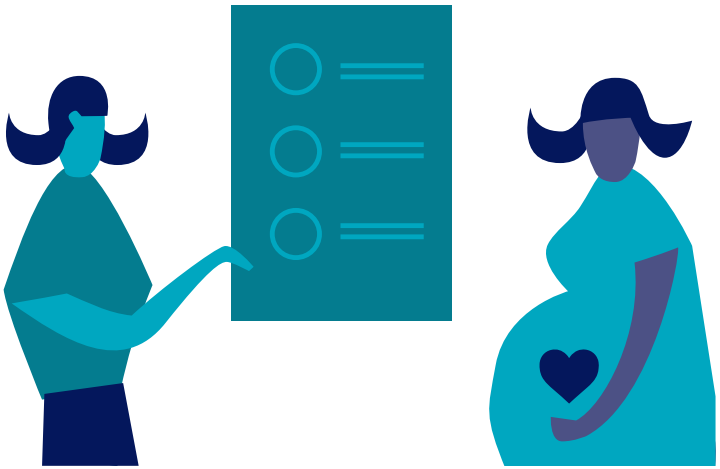
You should begin to have the conversation with the consumer and their parent or guardian early, if they are likely to continue these medicines into adulthood. You should:

- inform them of the balance of risks based on their specific condition, to support them to make an informed decision
- review their medicine annually
- consider alternative medicines if they are taking sodium valproate
- advise the consumer on the importance of using two methods of contraception once they reach menarche or become sexually active, and make them aware that they can seek contraception without their parent or guardian being present.

Information for pharmacists

When you are dispensing anti-seizure medicine for epilepsy, mental health, or pain to anyone of childbearing potential:

- dispense sodium valproate in the original packaging where appropriate, and with precautionary information indicating caution in pregnancy
- make sure that consumers have a copy of the 'Medicines for epilepsy, mental health, and pain could harm your unborn baby. Talk to your doctor about the risks – to you and your baby – and how to balance them' booklet, and that you go through this with them. Reinforce the need to use effective contraception throughout treatment without interruption
- if you are dispensing Epilim®, check that consumers are able to access the sodium valproate consumer information, and review it with them
- remind the consumer of the importance of taking sodium valproate at the recommended dose, and to contact their doctor if they are planning to have a baby or think they might be pregnant.



Checking you have been understood

It is important that you have a two-way conversation with the consumer, and you both understand what has been said. You should make sure that you give the consumer comprehensive information so they can make an informed decision.

It is a good idea to give the consumer an opportunity for a follow-up conversation, to give them a chance to think about what you have discussed and ask any further questions.

Checking you have been clear is the third step in the Three Step Model to better health literacy published by the Health Quality & Safety Commission.

Further details are available at:

The Health Quality & Safety Commission's three steps to better health literacy

http://safer.nz/STBHL

United States evidence

http://safer.nz/PMC3037129

Checklist

After your conversation with the consumer, you should make sure that you have given them information on:

- ☐ the balance of risk to their health, and that of the fetus, of taking these medicines
- ☐ the importance of using two forms of contraception
- ☐ the need to plan a pregnancy 6-12 months in advance
- ☐ the importance of taking 5mg daily of folic acid, 12 weeks before trying to get pregnant and for 12 weeks after conception
- ☐ the need to seek urgent medical advice in the event of an unplanned pregnancy.

Parents or guardians concerned about whether a child has been affected

If you have a parent or guardian who is concerned that an existing child may have been affected by anti-seizure/mood stabilising medicines during a previous pregnancy, consider a referral to a paediatrician.

You might also consider talking to the parent or guardian about whether their child can access support from ACC for a treatment injury. You can find out more about treatment injury claims in ACC's Treatment Injury Claim Lodgement Guide at www.acc.co.nz/treatmentsafety.

They can also contact the consumer organisation **Foetal Anti-Convulsant Syndrome NZ** for advice and support.

Website	www.facsnz.com
Phone	021 189 4483
Email	denise@facsnz.com

Reporting an adverse drug reaction

Phone	(03) 479 7247 to speak to a Medical Assessor at the Centre for Adverse Reactions Monitoring (CARM)
Online	Submit a report to CARM https://nzphvc.otago.ac.nz/report/
Yellow Card	A completed Yellow Card can be submitted to CARM via email, fax or mail which can be obtained from contacting CARM.
Email	carmnz@otago.ac.nz
Fax	(03) 479 7150

More information

Information for healthcare professionals

More information on medicines is available from

www.medsafe.govt.nz or www.nzformulary.org

Different risks of harm

http://safer.nz/Dec14SodVal

Sodium valproate in pregnancy

https://www.medsafe.govt.nz/safety/Alerts/Epilim.asp

Epilepsy in pregnancy

http://safer.nz/EpiPreg

Health Navigator

www.healthnavigator.org.nz/

Information for consumers

Remember to advise consumers of the availability of local support networks in your region.

Epilepsy Association of New Zealand
Website www.epilepsy.org.nz
Phone 0800 374 537
Email national@epilepsy.org.nz

Mental Health Foundation
Website www.mentalhealth.org.nz
Phone (09) 623 4810
Email info@mentalhealth.org.nz

Family Planning
Website www.familyplanning.org.nz
Email national@familyplanning.org.nz

Foetal Anti-Convulsant Syndrome NZ
Website www.facsnz.com
Phone 021 189 4483
Email denise@facsnz.com

Health Navigator
Website www.healthnavigator.org.nz/

Order this booklet

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

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Appendix: List of medicines covered by this advice

This is a list of some of the medicines commonly used to treat epilepsies, mental health, and pain, and some of the brand names under which they are available in New Zealand.

This is not a full list of all the medicines that are available. New medicines are added from time to time and brand names can change. Please check if you think a medicine is missing from the list.

Scientific name	Brand name
Carbamazepine	Tegretol®
Clobazam	Frisium®
Clonazepam	Paxam®, Rivotril®
Diazepam	DBL®
Ethosuximide	Zarontin®
Gabapentin	Neurontin®, Arrow- Gabapentin®
Lacosamide	Vimpat®
Lamotrigine	Logem®, Mogine®, Lamictal®, Arrow-Lamotrigine®, Motrig®
Levetiracetam	Keppra®, Everet®, Levetiracetam AFT®
Lorazepam	Ativan®
Medicinal cannabis	Sativex®

Scientific name	Brand name
Oxcarbazepine	Trileptal®
Phenobarbital	Phenobarbitone PSM®
Phenytoin	Dilantin Infatabs®
Pregabalin	Lyrica®
Primidone	Apo-Primidone®
Retigabine	Trobalt®
Rufinamide	Inovelon®
Sodium valproate	Epilim®
Topiramate	Topamax®, Topiramate Actavis®
Vigabatrin	Sabril®

Notes


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