


## Annual Risk Acknowledgement Form

	<p><b>Valproate has risks in pregnancy</b></p> <p>If a woman uses valproate while she is pregnant, her child can be harmed.</p> <p>Valproate is not to be used in women of childbearing age unless the conditions of the pregnancy prevention programme are fulfilled.</p>
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Name of person using valproate:

Date of birth:

NHS Number:

Name of responsible person (if applicable):

Relationship of the responsible person to the patient:

Name, role and signature of specialist:

Name of valproate user's GP:

Date:

This form expires 12 months from this date .....  
A new form should be completed at each annual review.

The specialist must provide this form to girls and women of childbearing age who are being treated with valproate (Epilim, Depakote, Convulex, Episenta, Epival, Kentlim, Orlept, Syonell, Valpal) – or their “responsible person”; a parent/guardian or person capable of giving consent on behalf of patients who are minors or without the capacity to make an informed decision or a person acknowledging that the treatment is in the best interests of the patient.




A copy of the completed and signed form will be kept in the patient record.

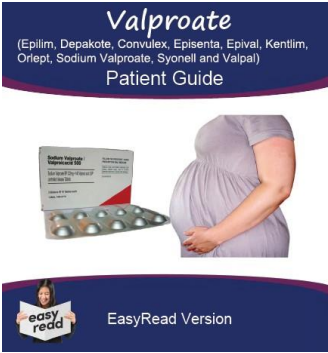


Copies of the completed and signed form should be given to the patient and their GP.

Give your patient (or their responsible person) a copy of the Patient Guide.

# Annual Risk Acknowledgement form for users of Valproate – Valproate has risks in pregnancy

**Step 1** – to be completed by the specialist when they consider a Pregnancy Prevention Programme is not needed.

	<p>The patient has not yet started her periods.</p> <p>I have asked the patient and family to tell me if this changes before the next annual review, which is on .....</p>	<input data-bbox="1394 618 1509 730" type="checkbox"/>
	<p>The patient is not at risk of getting pregnant because (insert reason):</p> <div data-bbox="590 1281 1232 1433" style="border: 1px solid black; height: 68px; width: 402px;"></div>	<input data-bbox="1394 1191 1509 1303" type="checkbox"/>
	<p>The patient is not likely to be sexually active before the next annual review because (insert reason):</p> <div data-bbox="587 1733 1225 1886" style="border: 1px solid black; height: 68px; width: 400px;"></div>	<input data-bbox="1394 1559 1509 1671" type="checkbox"/>

 <p><b>Valproate</b> (Epilem, Depakote, Convulex, Episenta, Epival, Kentlim, Oriep, Sodium Valproate, Syonell and Valpal) Patient Guide</p> <p>easy read EasyRead Version</p>	<p>I have given the patient or responsible person a copy of the Patient Guide.</p>	<input data-bbox="1401 338 1517 454" type="checkbox"/>
	<p>This form confirms that you or your carer, parent or responsible person understands the risks of using valproate.</p>	
	<p>Signature of the patient or responsible person:</p> <input data-bbox="628 1265 1485 1420" type="text"/>	

# Annual Risk Acknowledgement form – Valproate has risks in pregnancy

## Step 2 – Patient is of childbearing age and is at risk of pregnancy

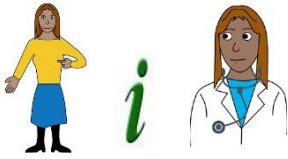
To be completed and signed by the specialist

I have explained the risks of using valproate in pregnancy

I confirm that the patient needs to take valproate because:

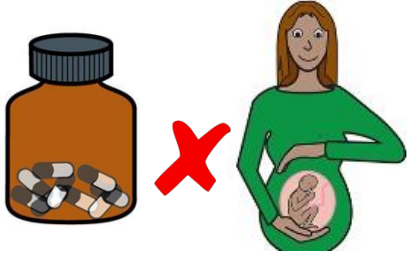
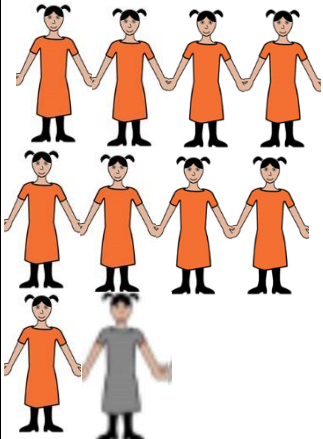
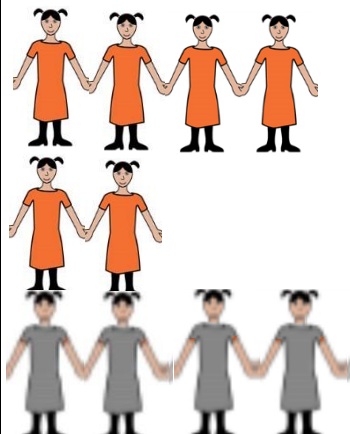


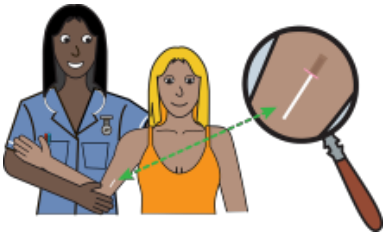

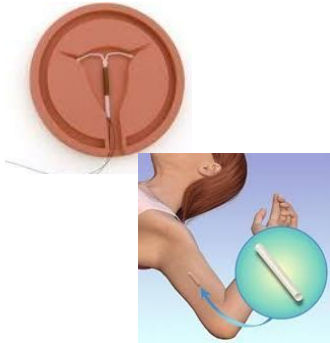

	<ul style="list-style-type: none"> <li>her condition does not respond well enough to other medicines,</li> </ul> <p><b>or</b></p>	<input type="checkbox"/>
	<ul style="list-style-type: none"> <li>she does not tolerate other treatments,</li> </ul> <p><b>or</b></p>	<input type="checkbox"/>
	<ul style="list-style-type: none"> <li>is in the process of changing medicines from valproate.</li> </ul>	<input type="checkbox"/>



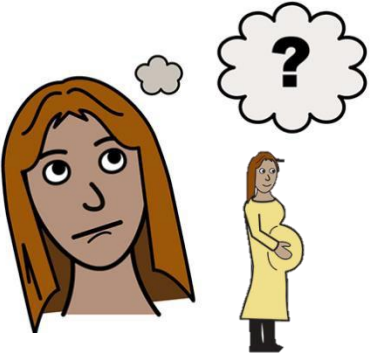



By ticking the boxes below I confirm that I have discussed the following information with the patient.




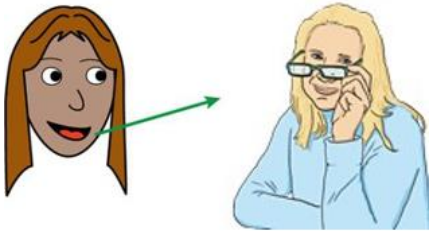

	<p>Valproate must not be used if the woman is pregnant.</p> <p>It can only be used in pregnancy if the woman has epilepsy and other medicines do not work for her.</p>	<input data-bbox="1380 488 1500 604" type="checkbox"/>
	<p>The overall risk in children exposed to valproate during pregnancy is a 1 in 10 chance of <b>birth defects</b>.</p> <p>A <b>birth defect</b> is where a baby didn't develop properly in the womb.</p>	<input data-bbox="1380 985 1500 1102" type="checkbox"/>
	<p>And a 4 in 10 chance of a wide range of development problems</p>	<input data-bbox="1380 1433 1500 1550" type="checkbox"/>

	<p>Choices to stop getting pregnant have been discussed.</p>	<input type="checkbox"/>
	<p>When using valproate condoms and the pill are not enough.</p>	<input type="checkbox"/>
	<p>The patient is using <b>effective contraception</b>.</p>	<input type="checkbox"/>
	<p>The patient must continue to use <b>effective contraception</b> all the time while she is taking valproate.</p>	<input type="checkbox"/>

	<p>The need for an annual review to discuss the need to keep taking valproate.</p>	<input data-bbox="1382 327 1501 443" type="checkbox"/>
	<p>The need to see her specialist as soon as she is thinking about getting pregnant to talk about changing to a different medicine before stopping contraception.</p>	<input data-bbox="1382 797 1501 913" type="checkbox"/>
	<p>The need to contact her GP straight away if she thinks she may be pregnant.</p>	<input data-bbox="1382 1245 1501 1361" type="checkbox"/>
	<p>The need for a negative pregnancy test result at the start of treatment and if needed during treatment.</p>	<input data-bbox="1382 1693 1501 1809" type="checkbox"/>






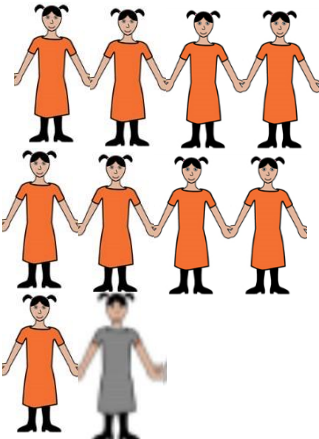
## In case of pregnancy, I confirm:

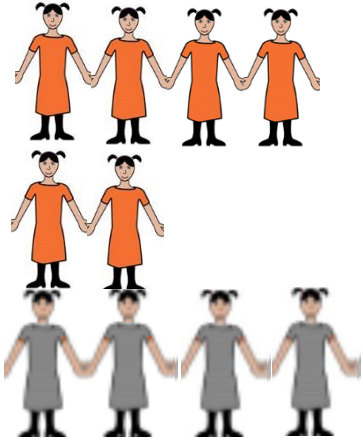
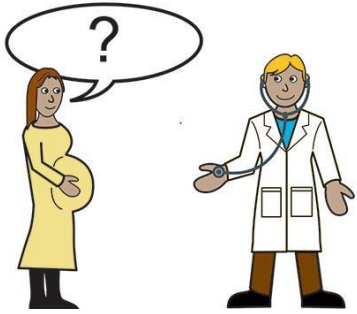
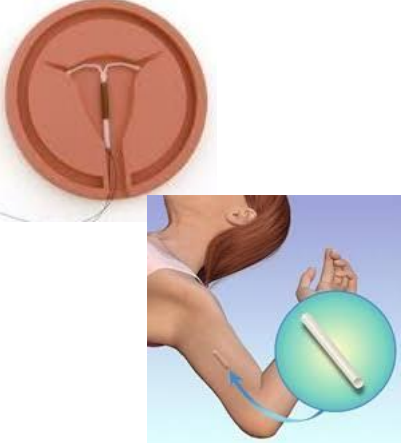

	<ul style="list-style-type: none"><li>• we have discussed options for switching treatment.</li></ul>	<input type="checkbox"/>
	<ul style="list-style-type: none"><li>• She is fully aware of the risks in pregnancy and has the opportunity to talk to someone about them.</li></ul>	<input type="checkbox"/>
	<ul style="list-style-type: none"><li>• The patient, carer or legal representative has a copy of the patient guide.</li></ul>	<input type="checkbox"/>


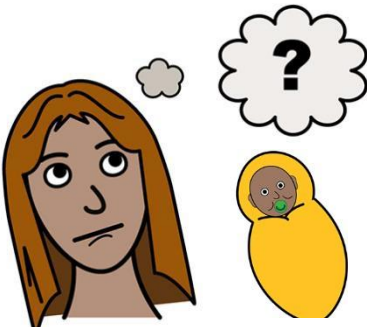

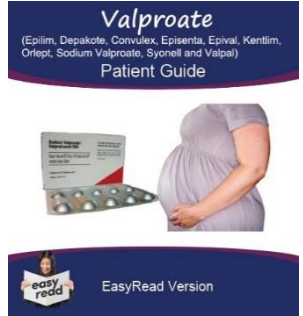
# Annual Risk Acknowledgement form – Valproate has risks in pregnancy

**Step 3** – to be completed by the patient or their responsible person

I have discussed this with my specialist and I understand:

	<p>Why I need to take valproate rather than another medicine.</p>	 <input type="checkbox"/>
	<p>That I should visit a specialist at least once a year to review whether valproate remains the best medicine for me.</p>	<input type="checkbox"/>
	<p>1 in 10 children will have <b>birth defects</b> if a mother takes valproate during pregnancy.</p> <p>A <b>birth defect</b> is where a baby didn't develop properly in the womb.</p>	<input type="checkbox"/>

	<p>4 in 10 children will have development problems.</p>	<input type="checkbox"/>
	<p>That I should have a pregnancy test if my doctor or specialist thinks I should.</p>	<input type="checkbox"/>
	<p>Why I must use <b>effective contraception</b> all of the time while I am taking valproate.</p> <p>The doctor explained to me that options for effective contraception include: using a coil, contraceptive implant.</p>	<input type="checkbox"/>
	<p>Condoms or the pill on their own are not good enough.</p>	<input type="checkbox"/>

	<p>I understand the choices for effective long-term contraception,</p> <p>or</p> <p>I have made plans to talk about it with someone who can give me advice.</p>	<input data-bbox="1380 347 1492 459" type="checkbox"/>
	<p>I will need to talk to my doctor as soon as I start thinking about getting pregnant.</p> <p>This is to make sure I have time to change medicine before I get pregnant.</p>	<input data-bbox="1380 817 1492 929" type="checkbox"/>
	<p>That I should see the doctor as soon as possible if I think I am pregnant.</p>	<input data-bbox="1380 1276 1492 1388" type="checkbox"/>
	<p>That I have a copy of the Patient Guide and know where I can find more information.</p>	<input data-bbox="1380 1724 1492 1836" type="checkbox"/>

## If you are pregnant

	<p>I confirm that I have talked about other treatments.</p>	<input type="checkbox"/>
	<p>I am fully aware of the risks while I am taking valproate.</p> <p>I have talked to somebody about the risks.</p>	<input type="checkbox"/>

Name of person using valproate:

**Signature:**

Date:

Name of responsible person:

Relationship of the responsible person to the patient:

**Signature:**

Date: