

## Valproate Survey 2020

### Background

In 2017 Epilepsy Action, Epilepsy Society and Young Epilepsy conducted a survey of women and girls with epilepsy who take valproate as a medicine and their parents and carers. The results showed that 1 in 5 (18%) women taking valproate were unaware that taking it during pregnancy can harm an unborn baby.

On 24 April 2018, the Medicines and Healthcare products Regulatory Agency (MHRA) changed the licence for valproate medicines in the UK. Valproate must no longer be prescribed to women or girls who are able to become pregnant unless they are on the Pregnancy Prevention Programme (PPP).

As part of the PPP, the prescriber must make sure the woman or girl understands the risk if she became pregnant while taking the medicine. The MHRA have produced materials to support healthcare professionals informing women on valproate of the risks in pregnancy. These include: a 'Prevent: valproate pregnancy prevention' card about use of valproate and pregnancy which should be given out with a prescription of valproate; a booklet, Prevent: A Patient Guide for healthcare professionals to give to patients; and a patient information leaflet (PIL) which should be provided with any medicine containing valproate.

Women must also be aware of the need to take contraception while on valproate. A risk acknowledgement form must be completed and signed during a review, which must take place at least once a year.

Between October 2019 and January 2020, Epilepsy Action worked with Epilepsy Society and Young Epilepsy to conduct another survey of women who have taken or who are taking valproate, since the introduction of the PPP. We surveyed women and girls who have taken valproate since 1 August 2018, and who therefore should have seen a health professional in that time. The report below explains the findings of the survey, based on the 751 responses we received. Of these, 519 were taking valproate at the time of the survey and 51 had been prescribed it in the past but stopped after 1 August 2018. 56 respondents were parents or carers of girls under 13 years old. These responses have not been included in the results below as this age group is subject to different prescribing guidelines.

The survey results reported below are based on the responses of these 514 respondents.

### Key Findings

#### Awareness

- 11% (64/514) of survey respondents were unaware that taking valproate in pregnancy can, in some cases, cause serious birth defects

- 18% (105/514) of respondents were unaware that taking valproate in pregnancy can, in some cases, cause learning and development problems in children
- Only 47% (239/514) of survey respondents said they had heard of the PPP, despite many of these women being aware of the risks of taking valproate during pregnancy and having received some of the programme materials

### **Pregnancy Prevention Programme**

- 11% (56/514) of respondents said they had not received any of the PPP information resources from their healthcare professional (excluding pharmacists)
- 57% (225/392) of women who were aware of the PPP were either satisfied or very satisfied with the PPP. This is in comparison to 16% (61/392) either not very satisfied or not at all satisfied (and 27% (106/424) not sure, 24% (122/514) who did not know about the PPP)
- 10 women in the UK were prescribed valproate for the first time, but were not signed up, whilst 79 women continued taking valproate without being signed up to the pregnancy prevention programme
- Only 46% (237/514) of women had received the Prevent card of whom 94% (222/237) of respondents stated that they fully understood the prevent card.
- Only 42% (214/514) had received the Prevent booklet of whom 94% (202/214) understood the prevent booklet.
- 75% (385/514) had received the patient information leaflet of whom 90% (346/385) fully understood the patient information leaflet

### **Annual Risk Acknowledgement Form**

- Nearly half of respondents 47% (239/514) said they had not been asked to sign the Annual Risk Acknowledgement Form
- This figure was 77% (43/56) for the women who had not received any of the PPP materials

### **Healthcare professionals**

- Only 55% (233/514) had had a discussion with a health professional about valproate since 1 August 2018
- Of the women who saw a healthcare professional in the last year, 25% (66/261) reported that their GP did not discuss valproate, 21% (72/345) said their paediatrician or neurologist did not discuss valproate, and 16% (28/175) said their epilepsy specialist nurse did not discuss valproate

### **Women who have received no Pregnancy Prevention Programme information**

- 56 women are taking valproate but said they had not received any of the PPP material from their healthcare professional (11% of respondents to the survey)
- Just over a third (19/56, 34%) of these women were unaware that taking valproate in pregnancy can, in some cases, cause serious birth defects, and 43% (24/56) were unaware about the risks of learning and development problems. This compares to 12% and 18% respectively in the overall responses, and represents a huge difference in the level of awareness
- Only 13 of these women said they had had a recent discussion (on or after 1 August 2018) with a healthcare professional about the risks associated with taking valproate during pregnancy

- Even more concerning is that 8 of these women were taking valproate at the time of the survey and said they were not signed up to the PPP despite deciding to continue with the medication
- In addition, one woman was prescribed valproate for the first time, but was not signed up to the PPP

### **Valproate dispensing from the pharmacist**

- Just under half of respondents (49%, 251/514) said they had had no discussion with their pharmacist about the risks associated with taking valproate during pregnancy. Only 14% (72/514) said they had this discussion every time they collected a prescription
- 29% (150/514) of respondents stated that when their valproate was dispensed in a plain package, the box never had a sticker with the warning pictogram. Only 60% (306/514) of respondents stated that a prescription in a manufacturer's packaging always included the warning pictogram
- Over half (51%, 261/514) of respondents said they had never received the Patient Card from their pharmacist when receiving their prescription

### **Implications of findings**

When women said they had received PPP information materials, most understood the information provided. In addition, more than half the women who had heard of the PPP were satisfied that the programme is fair for women with epilepsy

However, this means that there are women taking valproate who are still not aware of these risks. Despite the introduction of the PPP in 2018, the results suggest that the level of awareness of the risks has not improved since 2017, when 18% of women who were taking valproate or had taken it recently, were not aware of the risks.

There are still too many women reporting that they had not had a discussion with a healthcare professional about the risks of valproate use in pregnancy. It is clear from the survey results that communicating the risks to women remains an issue. There are still too many women reporting that they have not had a discussion with their GP (25%), neurologist or paediatrician (21%), or epilepsy specialist nurse (16%).

It is also concerning that a significant proportion of women reported that they have continued taking, or been prescribed valproate, without being signed up to the Pregnancy Prevention Programme. 10 women in the UK were prescribed valproate for the first time, but weren't signed up, whilst 86 women continued taking valproate without being signed up to the Pregnancy Prevention Programme.

In addition, some of the comments from individual respondents have highlighted other issues with the programme. For example, a number of women stated that they do not require contraception due to their sexuality, or the fact that their husband has had a vasectomy. These women often felt that their personal circumstances were ignored. Some respondents called for further support for women who are unable to switch medications,

and want to start a family. Some women also stated that they felt that they are denied the right to choose their own treatment.

## Regional comparison

	UK	England	Wales	Scotland	Northern Ireland
Awareness of risks of birth defects/learning and development problems	89%/82%	88%/82%	93%/86%	90%/82%	89%/81%
Not signed Annual Risk Acknowledgment Form	47%	47%	32%	49%	58%
Heard of PPP	47%	47%	46%	54%	35%
Pharmacist never discussed risks	49%	47%	47%	60%	73%
Satisfied with PPP	44%	44%	50%	41%	42%

- The results in England were in line with the overall numbers for the UK.
- It must be noted that the numbers reported for Wales (47), Scotland (57) and Northern Ireland (37) are low and so must be treated with caution.
- Looking at regional data Wales is performing better than other areas with regards to making sure women aware of the risks of both physical birth defects and learning and development problems.
- Women in Wales stated that they are more aware of the risks of birth defects and learning difficulties, (93% and 86% compared to 89% and 82% nationally). Women in Wales are also much more likely to have been asked to sign the Annual Risk Acknowledgement Form. 61% of respondents in Wales stated that they had been asked to sign, compared to 41% nationally (in Northern Ireland only 23% had been asked to sign, and 33% in Scotland).
- Women in Northern Ireland were more likely to have not received information about Prevent (69% of women in Northern Ireland had received a patient information leaflet, 27% received a prevent card, and 35% received a prevent booklet).
- Women in Northern Ireland were less likely to have received advice about the risks of taking valproate from a healthcare professional. Only 50% had such a discussion with their GP (75% nationally), 75% with a neurologist (79% nationally), and 25% with an epilepsy specialist nurse (84% nationally). Women in both Wales and Scotland were also more likely to have had such a conversation than women in Northern Ireland.

- Women in Northern Ireland were more likely to be worried or confused after discussions with their healthcare professional (60% compared to 32% nationally). However, women in Scotland and Wales were less likely to be worried or confused (26% and 21% respectively).
- 14% of women who had not received any information from healthcare professionals came from the East Midlands. This compared to 7% of respondents from the East Midlands overall, suggesting that there may be a issue in this region.

## Conclusions

More work is needed to make sure that all women taking valproate are aware of the risks of taking the medication during pregnancy and of the Prevent programme.

The biggest concern highlighted by the survey is that despite the licensing conditions for valproate requiring a prescription only to be made after the Annual Risk Acknowledgement Form has been signed and completed, half of all respondents taking valproate said they had never been asked to sign one.

It is also very concerning that there is a cohort of 56 women (11% of respondents to the survey) who said they had not received any of the Pregnancy Prevention Programme (PPP) materials from their healthcare professional.

It is clear from the results of our survey that more needs to be done to explain both the Pregnancy Prevention Programme, and the risks of taking valproate during pregnancy, particularly in Northern Ireland, and East Midlands.

More work is also needed to ensure that healthcare professionals are discussing the risks of taking valproate during pregnancy. There are still too many women reporting that they had not had a discussion with their GP (25%), neurologist (21%), paediatrician (18%) or epilepsy specialist nurse (16%).

Distribution of the patient information is lacking both within the healthcare setting and pharmacy and further steps are required to ensure this material is distributed.

The more information women receive the more satisfied they are with the programme, and importantly, the more aware they are of the risks of taking valproate during pregnancy.

Further consideration should also be given to concerns many respondents raised about the restrictions placed on them by the PPP, and being required to use unsuitable contraceptives.