

Template letters for patients taking valproate

Introduction

- **Valproate** is used in the treatment of epilepsy and bipolar disorder. It may also be used for other conditions, such as migraine, where this is considered off-label.
- All healthcare professionals who prescribe, review, or monitor valproate must be familiar with the **Medicines and Healthcare products Regulatory Agency (MHRA) safety alerts** and should have read the accompanying **Guide for Healthcare Professionals**.
- Additional regulatory changes were introduced through a **National Patient Safety Alert (NatPSA)** issued in **November 2023**, which came into effect in **January 2024**. These measures apply specifically to **oral valproate preparations**.
- The updated guidance places greater requirements on the prescribing of valproate for **people of childbearing potential under the age of 55**, including the need for **two independent specialists** to complete and sign the **Annual Risk Assessment Form (ARAF)**.
- The most recent regulatory changes also apply to **men under 55 years of age who are newly initiated on valproate**.
- Some individuals who do not identify as female may still be of childbearing potential. To ensure clarity and consistency, this guidance uses the following patient groups:
 - **Group 1:** Girls, women, trans men and non-binary people of childbearing potential under 55 years of age
 - **Group 2:** Boys, men, women and non-binary people **not** of childbearing potential under 55 years of age

About these templates

These templates have been developed by the **Cambridgeshire and Peterborough Valproate Safety and Implementation Group**, with input from Consultant Neurologists and Psychiatrists (adult and paediatric), Epilepsy Specialist Nurses, General Practitioners, Specialist Pharmacists and Pharmacy Technicians, and local Sexual Health Services.

TEMPLATE LETTER 1 — Group 1 Patients (Primary Care Annual Review)

Girls, women, trans men and non-binary people of childbearing potential under 55

Dear [Insert patient name],

We are writing to let you know that you are currently prescribed a medicine called **valproate** (also known by brand names including *Belvo®*, *Convulex®*, *Depakin®*, *Depakote®*, *Dyzantil®*, *Epilim®*, *Epilim® Chrono*, *Epilim® Chronosphere*, *Episenta®*, *Epival®*, *Orlept®*, *Sodium valproate*, *Syonell®*, *Valproic acid*).

Valproate is commonly used to treat epilepsy, bipolar disorder or, in some cases, to prevent migraine. **Please do not stop taking valproate without discussing this with your specialist first**, as your condition could become worse.

Valproate can **seriously harm an unborn baby** if taken during pregnancy. We have enclosed further information about your medicine and the risks associated with valproate use.

We would like to invite you for an annual review. This will allow us to discuss your treatment, ensure it continues to be prescribed safely, and answer any questions you may have.

Please be reassured that **your treatment decisions, including contraception, remain your choice** and we will not change your valproate or take you off valproate against your wishes.

Yours sincerely,

[Practice/Clinician details]

TEMPLATE LETTER 2 — Group 1 Patients (Primary Care Review + Referral to Secondary Care)

Dear [Insert patient name],

We are writing because you are currently prescribed **valproate** (brand names include *Belvo*®, *Convulex*®, *Depakin*®, *Depakote*®, *Dyzantil*®, *Epilim*®, *Epilim*® *Chrono*, *Epilim*® *Chronosphere*, *Episenta*®, *Epival*®, *Orlept*®, *Sodium valproate*, *Syonell*®, *Valproic acid*).

Valproate is used to treat epilepsy, bipolar disorder or occasionally to prevent migraine.

Please do not stop taking valproate without speaking to your specialist first, as stopping suddenly may cause your condition to worsen.

Valproate can **seriously harm an unborn baby** if taken during pregnancy. Enclosed is further information about these risks.

We would like to arrange a review in the practice and, if you are not already under a specialist, we can discuss whether a referral to secondary care is needed for your annual assessment.

Please be reassured that **your treatment decisions, including contraception, remain your choice** and we will not change your valproate or take you off valproate against your wishes.

Yours sincerely,

[Practice/Clinician details]

TEMPLATE LETTER 3 — Group 2 Patients (Primary Care Annual Review)

Boys, men, trans women and non-binary people not of childbearing potential under 55

Dear [Insert patient name],

We are writing to let you know that you are prescribed **valproate** (also known by brand names such as *Belvo®*, *Convulex®*, *Depa kin®*, *Depakote®*, *Dyzantil®*, *Epilim®*, *Epilim® Chrono*, *Epilim® Chronosphere*, *Episenta®*, *Epival®*, *Orlept®*, *Sodium valproate*, *Syonell®*, *Valproic acid*).

Valproate is used to treat epilepsy, bipolar disorder or, in some cases, to prevent migraine.

Please do not stop taking valproate without speaking to your specialist, as your condition may worsen.

Valproate is known to cause harm to an unborn baby when taken during pregnancy. Recent evidence suggests there may also be **possible reproductive risks associated with paternal exposure**.

Further information about these risks is enclosed.

It is recommended that **both you and your partner use effective contraception during treatment and for at least three months after stopping valproate**.

If you are planning a family in the next 12 months, or wish to discuss alternative treatment, please let your doctor know as soon as possible so a review can be arranged.

Yours sincerely,

[Practice/Clinician details]

TEMPLATE LETTER 4 — Group 1 Patients (Paediatrics / Paediatric Neurology)

Up to 18 years old, post-menarche

Dear *[Insert patient name / Parent or Guardian]*,

We have received a request from your child's GP for a specialist opinion, as your child is taking **valproate** for epilepsy. We have added them to the waiting list for a paediatric clinic appointment and will send confirmation of the date and time a few weeks beforehand.

Your child's GP may already have discussed the national safety guidance for valproate use and provided an information leaflet. If not, we have enclosed a copy of the **Valproate Patient Guide**.

Please **do not stop your child's valproate without discussing this with a specialist first**, as their condition may worsen if treatment is stopped suddenly.

If you have any questions before the appointment, please contact your child's GP.

Yours sincerely,

[Paediatric department details]

TEMPLATE LETTER 5 — Group 1 Patients (Neurology)

Dear *[Insert patient name]*,

Your GP has asked us to review your treatment with **valproate**. You have been added to the waiting list for a neurology clinic appointment and will receive confirmation of the date and time in the coming weeks.

We hope your GP has already discussed the national guidance on the safe use of valproate and given you a copy of the **Valproate Patient Guide**. If not, one is enclosed.

If you could become pregnant and are not using contraception, it is important that you do not become pregnant while taking valproate, as it can **seriously harm an unborn baby**.

Please **do not stop taking valproate without speaking to your specialist**, as your condition may worsen.

Please be reassured that **your treatment decisions, including contraception, remain your choice** and you will not be taken off valproate against your wishes.

If you have questions before your appointment, please contact your GP.

Yours sincerely,

[Neurology department details]

TEMPLATE LETTER 6 — Group 1 Patients (Mental Health Services)

Dear *[Insert patient name]*,

Your GP has asked us to review your treatment with **sodium valproate**. We have added you to the waiting list for a mental health service appointment and will write to you with the date and time a few weeks beforehand.

We hope your GP has explained the national safety guidance for valproate use in people under 55 and provided an information leaflet. If not, one is enclosed.

If you could become pregnant and are not using contraception, it is important that you avoid pregnancy while taking valproate, as it can **seriously harm an unborn baby**.

Please **do not stop taking valproate without discussing this with your specialist first**, as your condition may worsen.

If you have any questions before your appointment, please contact your GP.

Yours sincerely,

[Mental health service details]

Document ratification details

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