# Report a Side Effect

**Report a suspected side effect or adverse event involving a Pharmanovia medicine.**

If you or someone you care for has experienced a possible side effect while using a Pharmanovia medicine, you can report it to us even if you are not sure that the medicine caused it. You may complete this form in your own language.

For medical advice, please contact your healthcare professional. For urgent medical assistance, contact your local emergency service.

## 1 Reporter and patient

### Reporter details

**Who is making this report?**

- ☐ Patient
- ☐ Healthcare professional
- ☐ Parent or caregiver
- ☐ Other

**Name**

**Email**

**Telephone** Please include your country dialling code, for example +44.

**Reporter country**

### Patient details

**Patient initials or name**

**Age or date of birth** For example: 45 years, 6 months, or DD/MM/YYYY.

**Sex**

- ☐ Female
- ☐ Male
- ☐ Other
- ☐ Prefer not to say

**Patient country**

## 2 Medicine

Please list up to five medicines relevant to this report. Include the medicine name and any other information you know. If you need more space, attach an additional page.

| No. | Medicine name | Strength and dose | Start date | Stop date | Batch / lot number |
|---|---|---|---|---|---|
| 1 | *name* | *e.g. 10 mg once daily* | *DD/MM/YYYY* | *DD/MM/YYYY* | *if known* |
| 2 | *name* | *e.g. 10 mg once daily* | *DD/MM/YYYY* | *DD/MM/YYYY* | *if known* |
| 3 | *name* | *e.g. 10 mg once daily* | *DD/MM/YYYY* | *DD/MM/YYYY* | *if known* |
| 4 | *name* | *e.g. 10 mg once daily* | *DD/MM/YYYY* | *DD/MM/YYYY* | *if known* |
| 5 | *name* | *e.g. 10 mg once daily* | *DD/MM/YYYY* | *DD/MM/YYYY* | *if known* |

Date format: DD/MM/YYYY. If you do not know the exact treatment start or stop date, leave the date blank and tell us what you know in the description of what happened.

**Additional medicine information (optional)**

Use this space for formulation, route, reason for use, or any other medicine details you think may be relevant.

## 3 What happened?

**Description of the suspected side effect / adverse event**

Please describe what happened in as much detail as you can.

**When did it start?** DD/MM/YYYY, if known

**Is it still ongoing?**

☐ Yes ☐ No ☐ Not known

**Seriousness and outcome, if known**

For example: hospitalisation or prolonged hospitalisation, a life-threatening event, persistent or significant disability, congenital anomaly/birth defect, death or another medically important condition. Please also tell us the outcome, if known (for example recovered, recovering or not recovered).

**Other relevant information** Optional - include anything else you feel is relevant.

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# Review and send

Please check that the information you have provided is as complete as possible before sending the form.

## Use of information

I understand that the information provided in this form, including personal and health information, will be collected and used by Pharmanovia for pharmacovigilance and patient-safety purposes. This may include assessment and processing of the adverse event report and sharing relevant information with health authorities and other parties involved in pharmacovigilance, where required by applicable laws and regulations.

## Contact permission

☐ I agree that Pharmanovia may contact me using the contact details provided in this form to request additional information or clarification regarding this adverse event report.

This is optional. You can still send your report if you do not tick this box.

## Send the completed form

Please email the completed form to:

**medinfo@pharmanovia.com**

You may complete this form in your own language.

**Please note**

For medical advice, please contact your healthcare professional.

For urgent medical assistance, contact your local emergency service.