Pomalidomide Pregnancy Prevention Programme Patient Guide

Information for Patients taking Pomalidomide

Ireland

Version 4.0
Approved by HPRA: 01-DEC-2025

This Guide Contains Information About:

Preventing harm to unborn babies: If pomalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Pomalidomide Pregnancy Prevention Programme: This Programme is designed to make sure that unborn babies are not exposed to pomalidomide. It will provide you with information about what to expect from your treatment, and explain the risks and your responsibilities.

This guide will help you understand what to do before, during and after taking pomalidomide.

This guide will not give you information about multiple myeloma.

You should ask your prescriber if you have any questions.

Warning: Severe life-threatening birth defects. If pomalidomide is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

Pomalidomide must never be used by women who are pregnant, as just one capsule can cause severe birth defects.

Pomalidomide must never be used by women who are able to become pregnant unless they follow the Pomalidomide Pregnancy Prevention Programme.

Pomalidomide passes into men's semen, and is expected to cause severe birth defects or death to an unborn baby. So there is a risk if you have unprotected sex with a woman who can become pregnant.

For your own health and safety, please read this guide as well as the Package Leaflet that comes with your medicine, carefully. If you do not understand something, please ask your prescriber for further explanation.

For complete information on all possible side effects please read the Package Leaflet that comes with your pomalidomide capsules.

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This guide also contains important information about the requirement to avoid blood donation during treatment, the safe handling of pomalidomide and the safe disposal of unused pomalidomide capsules.

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Introduction

Pomalidomide is used to treat adults with a type of cancer called 'multiple myeloma'. Pomalidomide works in a number of different ways:

- by stopping the cancer cells developing
- by stimulating the immune system to attack the cancer cells.
- by stopping the formation of blood vessels supplying the cancer cells

Pomalidomide is either used with:

- two other medicines - called 'bortezomib' (a type of chemotherapy medicine) and 'dexamethasone' (an anti-inflammatory medicine) in people who have had at least one other treatment - including lenalidomide.

Or

- one other medicine - called 'dexamethasone' in people whose myeloma has become worse, despite having at least two other treatments - including lenalidomide and bortezomib.

Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe, life-threatening birth defects. If pomalidomide is taken during pregnancy, a teratogenic effect is expected.

Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans. Therefore precautions must be taken to avoid exposure to pomalidomide in an unborn baby.

This guide is part of the Pomalidomide Pregnancy Prevention Programme, which is necessary because if pomalidomide is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

This guide contains important information about the Pomalidomide Pregnancy Prevention Programme. You must read the information carefully and before starting treatment you should:

- Understand the risks of pomalidomide treatment.
- Understand the guidelines for taking pomalidomide safely, including how to prevent pregnancy.
- Please ensure you read the Package Leaflet before you use the medication as it contains information on all the side effects that can occur with pomalidomide.
- Understand what to expect during your initial and follow-up consultations with your prescriber.
- Discuss with your prescriber, who will have explained to you, the risks of pomalidomide treatment and specific instructions that you must follow.
- Please make sure that you understand what your prescriber has told you before starting pomalidomide.

If you don't understand something, please ask your prescriber for further explanation.

Pomalidomide and Birth Defects

All medicines can cause unwanted effects or 'side effects'. An extremely important side effect of pomalidomide is that if taken during pregnancy, it can cause severe birth defects or death to an unborn baby. The birth defects include shortened arms or legs, malformed hands or feet, eye or ear defects, and internal organ problems. This means pomalidomide must never be taken by:

- Women who are pregnant
- Women who could become pregnant, unless they follow the Pomalidomide Pregnancy Prevention Programme

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Pomalidomide and Other Possible Side Effects

Like all medicines, pomalidomide can cause side effects, although not everybody gets them. Some side effects are more common than others and some are more serious than others. Ask your prescriber or pharmacist if you would like more information and refer to the Package Leaflet. Most side effects are temporary and can be easily prevented and treated. The most important thing is to be aware of what to expect and what to report to your prescriber. It is important that you talk to your prescriber if you have any side effects during pomalidomide treatment.

Reporting of Side Effects

If you get any side effects, talk to your prescriber, pharmacist or nurse. This includes any possible side effects not listed in this guide. You can also report side effects directly via the HPRA Pharmacovigilance website: www.hpra.ie.

Special Monitoring

Before and during the treatment with Pomalidomide you will have regular blood tests. This is because Pomalidomide may cause a fall in the number of blood cells that help fight infection (white cells) and in the number of cells that help to stop bleeding (platelets).

Your prescriber will ask you to have a blood test:

- Before treatment
- Every week for the first 8 weeks of treatment
- Then at least every month after that for as long as you are taking pomalidomide.

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As a result of these tests, your prescriber may change your dose of pomalidomide or stop your treatment. The prescriber may also change the dose or stop the medicine because of your general health.

Pregnancy Prevention Programme

You should tell your prescriber if you are pregnant or think you may be pregnant or are planning to become pregnant, as **pomalidomide is expected to be harmful to an unborn child.**

- Before starting pomalidomide treatment you should discuss with your prescriber whether or not there is any possibility that you could become pregnant. Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant.
- If you are able to become pregnant, you must follow all the necessary measures to prevent you becoming pregnant and ensure you are not pregnant during treatment. Before starting the treatment, you should ask your prescriber if you are able to become pregnant, even if you think this is unlikely.
- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Risk Awareness Form documenting that you have been informed of the requirements of the Pregnancy Prevention Programme. Women of childbearing potential will be informed NOT to become pregnant throughout the duration of treatment with pomalidomide and for at least 4 weeks after stopping pomalidomide.
- If you are able to become pregnant and even if you agree and confirm every month that you will not engage in heterosexual activity, you will have pregnancy tests under the supervision of your prescriber before treatment. These will be repeated at least every 4 weeks during treatment, during dose interruptions and at least 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilisation).

- If you are able to become pregnant, **unless you commit to absolute and continuous abstinence confirmed on a monthly basis**, you must use at least one effective method of contraception for at least 4 weeks before starting treatment, throughout the duration of the treatment (including dose interruptions), and for at least 4 weeks after stopping treatment. Your prescriber will advise you on appropriate methods of contraception as some types of contraception are not recommended with pomalidomide. It is essential therefore that you discuss this with your prescriber. If necessary, your hospital team can refer you to a specialist for advice on contraception.

- **Do not take pomalidomide** if you are pregnant, think you may be pregnant or are planning to become pregnant, as **pomalidomide is expected to be harmful to an unborn child.**

- If you suspect you are pregnant at any time whilst taking pomalidomide or in the 4 weeks after stopping treatment, you must stop pomalidomide immediately and immediately inform your prescriber. Your prescriber will refer you to a physician specialised or experienced in teratology for evaluation and advice.

Childbearing Potential Assessment

Before starting pomalidomide treatment you should discuss with your prescriber whether or not there is any possibility that you could become pregnant. Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant.

Female patients will be assessed by their prescriber for childbearing potential, and unless you fall into one of the following categories you must follow the contraceptive advice presented in the next section:

- You are at least 50 years old and it has been at least one year since your last period (if your periods have stopped because of cancer therapy or during breastfeeding, then there is still a chance you could become pregnant).

- Your womb has been removed (hysterectomy).
- Your fallopian tubes and both ovaries have been removed (bi-lateral salpingo oophorectomy).
- You have premature ovarian failure, confirmed by a specialist gynaecologist.
- You have the XY genotype, Turner syndrome or uterine agenesis.

You may need an appointment and tests with a specialist in female medicine to confirm that you cannot become pregnant.

Every woman who is able to become pregnant even if they are not planning to must follow the precautions detailed in this section.

Women of Childbearing Potential

Pomalidomide is expected to be harmful to the unborn child.

- Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans
- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Risk Awareness Form documenting that you have been informed of the requirement for you NOT to become pregnant throughout the duration of your treatment with pomalidomide and for at least 4 weeks after stopping pomalidomide.
- You should start your pomalidomide treatment as soon as possible after having a negative pregnancy test result.
- You should never share pomalidomide with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- You should not donate blood during treatment, during dose interruptions, or for at least 7 days after stopping treatment.

- For additional information, please refer to the Package Leaflet.
- You must never take pomalidomide if:
  - You are pregnant.
  - You are a woman who is able to become pregnant, even if you are not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.
- You must stop treatment and inform your doctor straight away if you have heterosexual intercourse without using an effective method of contraception.

If you experience any side effects whilst taking pomalidomide you should tell your prescriber or pharmacist.

Contraception to Prevent Pregnancy

If you are a woman who could become pregnant you must either:

- Use adequate contraception starting at least 4 weeks before pomalidomide treatment, during pomalidomide treatment, during any breaks in pomalidomide treatment and for at least 4 weeks after stopping pomalidomide treatment.

OR

- Agree you will not engage in sexual activity with a male partner starting at least 4 weeks before pomalidomide treatment, during pomalidomide treatment, during any breaks in pomalidomide treatment and for at least 4 weeks after stopping pomalidomide treatment. You will be asked to confirm this every month.

Inform the prescriber of your contraception that you are on pomalidomide.

Inform your prescriber of pomalidomide if you have changed or stopped the method of contraception.

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You should start your pomalidomide treatment as soon as possible after having a negative pregnancy test result and having received pomalidomide.

Not all types of contraception are suitable during pomalidomide treatment. You and your partner should discuss with your prescriber suitable forms of contraception that you both find acceptable. If necessary, your health care professional can refer you to a specialist for advice on contraception.

Males

Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. If pomalidomide is taken during pregnancy, a teratogenic effect is expected.

- **Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans**
- Pomalidomide passes into human semen. If your partner is pregnant or able to become pregnant, and she doesn't use effective contraception, you must use condoms throughout the duration of your treatment, during dose interruptions and at least 7 days after you stop pomalidomide even if you have had a vasectomy.
- Ask your prescriber to inform you on which are the effective contraceptive methods that your female partner can use.
- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Risk Awareness Form documenting that you have been informed of the requirement for your partner NOT to become pregnant throughout the duration of your treatment with pomalidomide and for at least 7 days after you stop pomalidomide
- You should never share pomalidomide with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.

- You should not donate blood, semen or sperm during treatment, during dose interruptions, or for at least 7 days after stopping treatment.
- If your partner does become pregnant whilst you are taking pomalidomide or within 7 days after you have stopped taking pomalidomide, you should inform your prescriber immediately and your partner should also consult her doctor immediately.
- For additional information, please refer to the Package Leaflet.

If you experience any side effects whilst taking pomalidomide you should tell your prescriber or pharmacist.

Women of Non-childbearing Potential

Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. If pomalidomide is taken during pregnancy, a teratogenic effect is expected.

- **Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans.**
- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Risk Awareness Form documenting that you are not able to become pregnant.
- You should never share pomalidomide with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- You should not donate blood during treatment, during dose interruptions, or for at least 7 days after stopping treatment.
- For additional information, please refer to the Package Leaflet.

If you experience any side effects whilst taking pomalidomide you should tell your prescriber or pharmacist.

Pomalidomide Treatment in All Patients

Before Starting Your Treatment:

Your prescriber will talk to you about what to expect from your treatment, and explain the risks and your responsibilities.

If there is anything you do not understand, please ask your prescriber to explain it again.

Before starting treatment your prescriber will ask you to read and sign a Risk Awareness Form, which confirms that while taking pomalidomide:

- You understand the risks of birth defects and the actions you must take to prevent this risk from occurring depending on whether you are a female patient who can become pregnant, a male patient or a female patient who cannot become pregnant.
- If you are able to become pregnant you will follow the necessary requirements to prevent pregnancy
- You understand the other important safety messages.
- As a male patient, you understand the need to use condoms during treatment (including dose interruptions) and for at least 7 days after stopping pomalidomide if your partner is pregnant or is of childbearing potential and not using effective contraception.

Your prescriber will include a copy in your medical file and provide a copy to you.

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Receiving Your Prescription

Your prescriber must complete a 'Prescription Authorisation Form' in addition to your prescription, which will be given to you to present at your nominated pharmacy or will be sent directly to your pharmacy each time you are prescribed pomalidomide. This form confirms that all of the Pregnancy Prevention Programme measures have been followed. Your pharmacist will review this documentation prior to ordering and dispensing your pomalidomide.

For women of childbearing potential your prescriber will write a prescription for no more than 4 weeks supply and you must have the medication dispensed within 7 days of the prescription date. A negative pregnancy test must also be confirmed on the prescription authorisation form before pomalidomide can be dispensed.

For women of non-childbearing potential and male patients your prescriber will write a prescription for no more than 12 weeks supply.

You will need to see your prescriber each time you need a repeat prescription.

Safety Measures During Treatment:

You must never take pomalidomide if you are allergic to pomalidomide or to any of the other ingredients contained in the capsule.

You should never share pomalidomide with anyone else.

You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.

You should not donate blood during treatment, during dose interruptions, or for at least 7 days after stopping treatment.

If you experience any side effects whilst taking pomalidomide you should tell your prescriber or pharmacist.

If you accidentally take too many capsules contact your prescriber immediately.

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If you forget to take your dose of pomalidomide on one day, then take the normal prescribed dose as scheduled on the next day. You should not adjust the dose to make up for a missing dose on previous days.

Let your prescriber know if you have missed any doses at your next visit.

For additional information please refer to the Package Leaflet.

Taking other medicines

Please tell your prescriber or pharmacist if you are taking or have recently taken any other medicines, including medicines bought without a prescription. If you are seeing a different prescriber or other healthcare professional for treatment (your dentist for example) you should tell them that you are taking pomalidomide and any other medications.

How to Take your Medication

Your pharmacist can give you help and advice on taking your medications. Some people find it helpful to mark on a calendar when they have taken their medicines each day or to set an alarm clock to remind them to take their medications.

- Your prescriber will prescribe a dose of pomalidomide suited to you.
- Always take pomalidomide exactly as your prescriber has told you. Check with your prescriber or pharmacist if you are not sure.
- Your prescriber may adjust your dose depending on the result of blood tests and any side effects you may experience.
- Do not take more capsules than your prescriber has prescribed. If in doubt, ask your prescriber or pharmacist for advice.
- Pomalidomide capsules should be swallowed whole, with a glass of water.
- Pomalidomide can be taken at any time of day but it should be taken at approximately the same time each day.
- Pomalidomide can be taken with or without food.

- Do not break, open or chew the capsules. If powder from a broken pomalidomide capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.

How to store pomalidomide safely

- Keep your pomalidomide in a safe place out of the reach and sight of children.
- Keep your pomalidomide capsules in the original box at room temperature.
- Do not use after the expiry date written on the box.

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End of Treatment Requirements

After completing your pomalidomide treatment, it is important that:

- You return any unused pomalidomide capsules to your pharmacist.
- You do not donate blood for at least 7 days.

Additional advice for women of childbearing potential:

- Continue using your method of contraception for at least a further 4 weeks.
- Your prescriber will perform a final pregnancy test after at least 4 weeks, unless it is confirmed you have had a tubal sterilisation.

Additional advice for male patients:

- If you have been using an effective contraceptive method, you must continue doing so for at least 7 days.
- If your female partner has been using an effective contraceptive method, she must continue doing so for at least 4 weeks.
- Do not donate semen or sperm for at least 7 days.

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Points to Consider for Handling the Medicinal Product: For Patients, Family Members and Caregivers

Do not share the medicinal product with anyone else, even if they have similar symptoms. Store them safely so that no-one else can take them by accident and keep them out of the reach of children.

Keep the blisters with the capsules in the original pack.

Care must be taken when removing capsules from the blister packaging to ensure that capsules are not broken. Please refer to the Package Leaflet that comes with your medicine for instructions on how to remove the capsule from the blister to reduce the risk of damage to the capsule. Please note the method of removal may differ depending on which pomalidomide product you have dispensed.

Healthcare professionals, caregivers and family members should wear disposable gloves when handling the blister or capsule. Remove gloves carefully to prevent skin exposure. Place in a sealable plastic polyethylene bag. Dispose of any unused medication in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule. Refer overleaf for further guidance.

When handling the medicinal product use the following precautions to prevent potential exposure if you are a family member and/or caregiver:

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule.
- Wear disposable gloves when handling product and or packaging (i.e. blister or capsule)
- Use the proper technique when removing gloves to prevent potential skin exposure (see over)

- Place gloves in sealable plastic polyethylene bag and dispose according to local requirements.
- Wash hands thoroughly with soap and water after removing gloves.
- Do not give pomalidomide to another person.

If a drug product package appears visibly damaged, use the following extra precautions to prevent exposure:

- If outer carton is visibly damaged **– Do Not Open**
- If blister strips are damaged or leaking or capsules are noted to be damaged or leaking
    - **Close Outer Carton Immediately**
- Place the product inside a sealable plastic polyethylene bag.
- Return unused pack to the pharmacist for safe disposal as soon as possible.

If product is released or spilled, take proper precautions to minimise exposure by using appropriate personal protection:

- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling clean the area thoroughly with soap and water and dry it
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag and dispose in accordance to local requirements for medicinal products

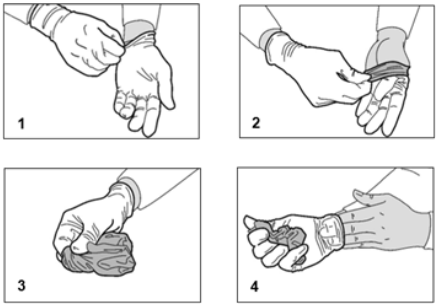
- Wash your hands thoroughly with soap and water after removing the gloves.
- Please report to the prescriber and/or pharmacist immediately.

If the contents of the capsule are attached to the skin or mucous membranes:

- If you touch the drug powder, please wash exposed area thoroughly with running water and soap.
- If the powder gets in contact with your eye, if worn and if easy to do, remove contact lenses and discard them. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs, please contact an ophthalmologist.

Proper Technique for Removing Gloves:

- Grasp outside edge near wrist (1)
- Peel away from hand, turning glove inside-out (2)
- Hold in opposite gloved hand (3)
- Slide ungloved finger under the wrist of the remaining glove, be careful not to touch the outside of the glove (4)
- Peel off from inside, creating a bag for both gloves.
- Discard in appropriate container.
- Wash your hands with soap and water thoroughly.



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Personal Notes

Please use this space to write down any questions for your prescriber for discussion at your next appointment.

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Check List

Please use this check list to confirm that you have understood all of the important information regarding your pomalidomide treatment.

All Patients

- ☐ Yes, I have received and understood all the information on the risks of birth defects associated with taking pomalidomide.
- ☐ Yes, I have received and understood all the information on the risks of other side effects associated with taking pomalidomide.
- ☐ Yes, I have understood that I must not donate blood during treatment (including dose interruptions), and for at least 7 days after stopping treatment.
- ☐ Yes, I understand that I need to sign the Risk Awareness Form before starting treatment.
- ☐ Yes, I have understood that I should never share pomalidomide with anyone else.
- ☐ Yes, I have understood that I should always return any unused capsules to the pharmacist for safe disposal as soon as possible.

Male Patients

- ☐ Yes, I have understood the need to use condoms during treatment, during dose interruption and for at least 7 days after stopping pomalidomide, if I have a female partner who is pregnant or is able to get pregnant and not using effective contraception.
- ☐ Yes, I have understood I must not donate semen or sperm during treatment (including during dose interruptions) and for at least 7 days after stopping pomalidomide.

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Female Patients who can become pregnant

- ☐ Yes, I will use one effective method of contraception for at least 4 weeks before starting pomalidomide, during therapy (even in the case of dose interruptions) and for at least 4 weeks after I have stopped pomalidomide treatment.
- ☐ Yes, I understand that I need to have a negative pregnancy test result before starting to take my treatment, and for at least every 4 weeks during treatment and at least 4 weeks after stopping treatment (except in the case of confirmed tubal sterilisation).

Remember, your pharmacist can give you help and advice on taking your medicines.

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This guide is produced as a collaborative project between Accord Healthcare Ltd., Clonmel Healthcare Ltd., Viatris Limited., AS Grindeks,Teva Pharmaceuticals Ireland. and Rowex Ltd. For further information, please refer to the Patient Information Leaflet (PIL) for the respective medicinal product or contact the relevant company as per table below.

Accord Healthcare Ltd

Email: medinfo@accord-healthcare.com

Tel: 0044 1271 385257

Clonmel Healthcare Ltd.

Email: medicalinformation@clonmel-health.ie

Tel: +353 (0)52 617 7777

Viatris Limited.

Email: info.ie@viatris.com

Tel: 0044 01707 853 000

AS Grindeks

Email: adrian.curley@grindeks.ie

Tel: +353 (0)87 298 8226

Teva Pharmaceuticals Ireland

Email: medinfo@tevauk.com

Tel: 0044 207 540 7117

Rowex Ltd

Email: mi.ireland@sandoz.net

Tel: 0877941968

Data Protection Contact Details

Please see below contact details for data protection queries for the relevant Marketing Authorisation Holder.

Accord Healthcare Ltd

Email: emena_compliance@accord-healthcare.com

Clonmel Healthcare Ltd.

Email: dpo@clonmel-health.ie

Viatris Limited.

Email: dataprivacy@viatris.com

AS Grindeks

Email: adrian.curley@grindeks.ie

Teva Pharmaceuticals Ireland

Email: EUprivacy@tevaeu.com

Rowex Ltd

Email: mi.ireland@sandoz.net