Revlimid® ▼
(lenalidomide)

Pregnancy Prevention Programme

Information for Patients taking lenalidomide

United Kingdom (UK)
Version 11

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

You can help by reporting any side effects you may get. Report the suspected side effect using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Side effects should also be reported to Bristol-Myers Squibb Medical Information on 0800 731 1736 or medical.information@bms.com.

Risk Management contact details:
Tel: 0808 156 3059
Fax: 0808 156 3058
Email: rmpukire@bms.com

Medical Information Queries:
Email: medical.information@bms.com

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This brochure contains information about:

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

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

Lenalidomide 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.

This brochure will help you understand what to do before, during and after taking lenalidomide.

This brochure will not give you information about multiple myeloma, myelodysplastic syndrome, mantle cell lymphoma or follicular lymphoma. You should ask your prescriber if you have any questions.

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

Lenalidomide must never be used by women who are pregnant, as just one capsule is expected to cause severe birth defects.

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

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

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

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

Contents

Introduction

Revlimid is the trade name for lenalidomide. Lenalidomide works by affecting the body's immune system and directly attacking the cancer. It works in a number of different ways:

- by stopping the cancer cells developing
- by stopping blood vessels growing in the cancer
- by stimulating part of the immune system to attack the cancer cells.

Lenalidomide is licensed in the United Kingdom for use in adults for:

- Newly diagnosed multiple myeloma - on its own to treat patients who have had a bone marrow transplant
- Newly diagnosed multiple myeloma - in combination with other medicines to treat patients who cannot have a bone marrow transplant
- Multiple myeloma - in combination with another medicine to treat patients who have had treatment before
- Myelodysplastic syndromes due to low- or intermediate-1-risk - used alone to treat patients when all the following apply:
  - need regular blood transfusions to treat low levels of red blood cells ('transfusion-dependent anemia')
  - have an abnormality of cells in the bone marrow called an 'isolated deletion 5q cytogenetic abnormality'. This means your body does not make enough healthy blood cells
  - other treatments used before are not suitable or do not work well enough.
- Mantle cell lymphoma - used alone to treat patients who have previously been treated with other medicines
- Previously treated follicular lymphoma - in combination with rituximab.

Lenalidomide is structurally related to thalidomide, which is known to cause severe, life threatening birth defects. Precautions must be taken to avoid exposure to lenalidomide in an unborn baby.

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

- Understand the risks of lenalidomide treatment. 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 lenalidomide
- Understand the guidelines for taking lenalidomide safely, including how to prevent pregnancy
- Understand what to expect during your initial and follow-up consultations with your prescriber
- Your prescriber will have explained to you the risks of lenalidomide treatment and specific instructions that you must follow
- Please make sure that you understand what your prescriber has told you before starting lenalidomide

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

Lenalidomide and Birth Defects

All medicines can cause unwanted effects or 'side effects'. An extremely important side effect of lenalidomide is that if taken during pregnancy, it is expected to 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 lenalidomide must never be taken by:

- Women who are pregnant
- Women who could become pregnant, even if you are not planning to become pregnant, unless they follow the Revlimid Pregnancy Prevention Programme

Lenalidomide and Other Possible Side Effects

Like all medicines, lenalidomide 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 lenalidomide treatment.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

<u>Reporting of Side Effects</u>

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed not listed in the Package Leaflet.

Adverse events can also be reported online via the Yellow Card website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

Side effects and suspected pregnancies should also be reported to Bristol-Myers Squibb Medical Information on 0800 731 1736 or medical.information@bms.com.

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 **lenalidomide is expected to be harmful to an unborn child.**

- 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 lenalidomide, 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 lenalidomide and for at least 4 weeks after stopping lenalidomide.
- 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 lenalidomide. 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
- If you suspect you are pregnant at any time whilst taking lenalidomide or in the 4 weeks after stopping, you must stop lenalidomide 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

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 considered to be a woman who is not able to become pregnant if you fall into one of the following categories:

- 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.

Contraception Methods for Women of Childbearing Potential

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

- **Lenalidomide 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 lenalidomide, 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 lenalidomide and for at least 4 weeks after stopping lenalidomide
- You should never share lenalidomide 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 treatment finishes
- For additional information, please refer to the Package Leaflet.
- You must never take lenalidomide 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.

- If you are a woman who could become pregnant you must either:
    - Use adequate contraception starting at least 4 weeks before lenalidomide treatment, during lenalidomide treatment, during any breaks in lenalidomide treatment and for at least 4 weeks after stopping lenalidomide treatment.

    OR

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

- Inform the prescriber of your contraception that you are on lenalidomide.
- Inform your prescriber of lenalidomide if you have changed or stopped the method of contraception.
- Before starting lenalidomide 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..
- You should start your lenalidomide treatment as soon as possible after having a negative pregnancy test result and having received lenalidomide.
- **Do not take Revlimid®** if you are pregnant, think you may be pregnant or are planning to become pregnant, **as Revlimid® is expected to be harmful to an unborn child.**

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

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

Contraception Methods for Males

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

- **Lenalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans**
- 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 lenalidomide, 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 lenalidomide and for at least 7 days after you stop lenalidomide
- You should never share lenalidomide 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
- Lenalidomide 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 lenalidomide even if you have had a vasectomy
- If your partner does become pregnant whilst you are taking lenalidomide or within 7 days after you have stopped taking lenalidomide, you should inform your prescriber immediately and your partner should also consult her physician immediately
- For additional information, please refer to the Package Leaflet.

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

Women of Non Childbearing Potential

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

- **Lenalidomide 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 lenalidomide, your prescriber will complete a Risk Awareness Form documenting that you are not able to become pregnant
- You should never share lenalidomide 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 lenalidomide, you should tell your prescriber or pharmacist.

Lenalidomide Treatment

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 lenalidomide:

- 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 lenalidomide if your partner is pregnant or is of childbearing potential and not using effective contraception.

Your prescriber will keep one copy for your medical file and provide one copy to you.

Safety Measures During Treatment

There are additional measures you must understand while taking lenalidomide.

- Please remember that your lenalidomide must only be used by you. Do not share your medicine with anyone else, even if they have similar symptoms to you
- Store your lenalidomide capsules safely, so no one else could take them by accident. Keep your lenalidomide capsules in the original box at room temperature
- Do not use after the expiry date written on the box. The expiry date refers to the last day of that month.
- Keep lenalidomide out of reach and sight of children.

Receiving Your Prescription

Your prescriber may provide you with a 'Prescription Authorisation Form' (PAF) that must be provided to the pharmacist, which confirms that all of the Revlimid Pregnancy Prevention Programme measures have been followed. Your pharmacist will ask to review this documentation prior to dispensing your lenalidomide. Alternatively, your prescriber may complete the PAF electronically, in which case the PAF will be sent directly to the pharmacist.

For women of childbearing potential, your prescriber will write a prescription for no more than 4 weeks supply, provided you have had a valid negative pregnancy test within 3 days prior to your prescription date and you must have the medication dispensed within 7 days of the prescription date.

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.

How to Take your Medication

Your pharmacist can provide 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 lenalidomide suited to you
- Always take your medication exactly how 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 doctor has prescribed. If in doubt, ask your prescriber or pharmacist for advice
- Lenalidomide capsules should be swallowed whole, with a glass of water
- The capsules should not be opened, broken or chewed
- Lenalidomide can be taken at any time of day but it should be taken at approximately the same time each day
- Lenalidomide can be taken with or without food.

What to do if you have taken more than the prescribed dose of lenalidomide:

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

What to do if you forget to take your lenalidomide:

If you forget to take your lenalidomide and you remember within 12 hours of the missed dose, you can take your lenalidomide as soon as you remember and continue with the next dose at the normal time. If it is more than 12 hours since the missed dose, leave out that dose altogether and take the next dose at the normal time.

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

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 lenalidomide and any other medications.

End of Treatment Requirements

After completing your lenalidomide treatment, it is important that:

- You return any unused lenalidomide 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 method 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 method of contraception, you must continue doing so for at least 7 days
- If your female partner has been using an effective method of contraception, she must continue doing so for at least 4 weeks
- Do not donate semen or sperm for at least 7 days.

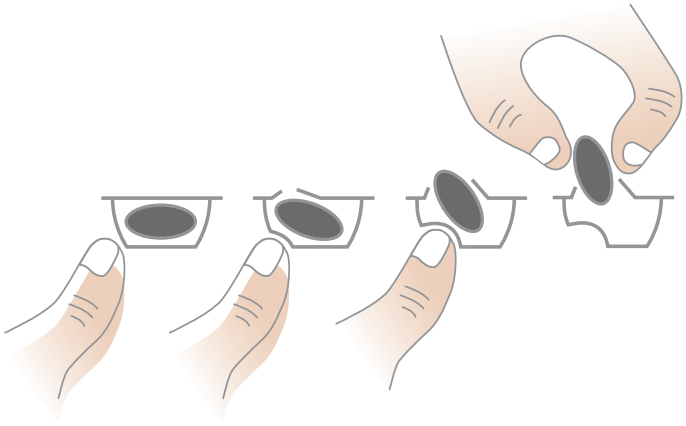
Points to Consider for Handling the Medicinal Product: for Patients, Family Members and Caregivers

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.

Capsules can occasionally become damaged when pressing them out of the blister, especially when the pressure is put onto the middle of the capsule. Capsules should not be pressed out of the blister by putting pressure on the middle. The pressure should be located at one site only, which reduces the risk of the capsule deforming or breaking (see figure below).

Healthcare professionals, family members and caregivers 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 regulations. 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 a sealable plastic polyethylene bag and dispose them according to local requirements
- Wash hands thoroughly with soap and water after removing gloves.
- Do not give lenalidomide to another person.

If a Drug Product Package Appears Visibly Damaged, Use the Following Extra Precautions to Prevent Exposure

- If the 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

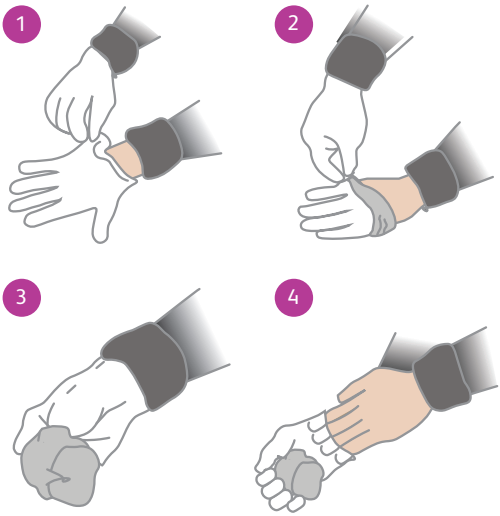
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling the powder
- Wear disposable gloves to clean up the powder
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add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



Personal Notes

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

Checklist

Please use this checklist to confirm that you have understood all of the important information regarding your lenalidomide treatment.

All Patients

- ☐ Yes, I have understood that I should never share lenalidomide 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.
- ☐ Yes, I have received and understood all the information on the risks of birth defects associated with taking lenalidomide.
- ☐ Yes, I have received and understood all the information on the risks of other side effects associated with taking lenalidomide.
- ☐ 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.

Male Patients

- ☐ Yes, I have understood the need to use condoms during treatment, during dose interruption and for at least 7 days after stopping lenalidomide, 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 lenalidomide.

Female Patients who can become pregnant

- ☐ Yes, I will use at least one effective method of contraception for at least 4 weeks before starting lenalidomide, during therapy (even in the case of dose interruptions) and for at least 4 weeks after I have stopped lenalidomide 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).

Special monitoring

Because lenalidomide can cause a drop in white blood cell and platelet counts, you will have regular blood tests during treatment. Your prescriber will also monitor how well your kidneys are working. You will have blood tests more frequently in the first few months when you start treatment.

Your prescriber may adjust your dose of lenalidomide or stop your treatment based on the results of your blood tests and on your general condition. If treatment has to be stopped for any reason, your prescriber will discuss other treatment options with you.

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

Bristol Myers Squibb™

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