



MEDICINES RECALL

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level Recall

Date: 13 January 2025

EL (25)A/02

Our Ref: DMRC-34132023

Dear Healthcare Professional,

Jubilant Pharmaceuticals NV

Irbesartan 150 mg film-coated tablets

PL 19156/0089

SNOMED Code 42375311000001101, 1126711000001102, 21123311000001108,
21123511000001102, 29880111000001105, 29880211000001104

Batch No	Expiry Date	Pack Size	First Distributed
IR222002A	08/2025	28	05/12/2023
IR222003A	08/2025	28	08/01/2024
IR222004A	09/2025	28	16/11/2023
IR222006A	09/2025	28	05/02/2024
IR222007A	09/2025	28	01/03/2024
IR222008A	09/2025	28	02/04/2024
IR224001A	03/2027	28	05/09/2024
IR224002A	03/2027	28	12/09/2024
IR224003A	03/2027	28	19/09/2024
IR224004A	06/2027	28	20/11/2024

Irbesartan 300 mg film-coated tablets

PL 19156/0090

SNOMED Code 42375511000001107, 1080311000001103, 21100511000001103,
21100611000001104, 21123811000001104, 21124111000001108,
29880311000001107, 29886711000001109

Batch No	Expiry Date	Pack Size	First Distributed
IR322001C	02/2025	28	05/12/2023
IR322002C	02/2025	28	01/02/2024
IR322003A	08/2025	28	16/11/2023
IR324002A	06/2027	28	11/11/2024
IR324003A	06/2027	28	26/11/2024
IR324004A	06/2027	28	06/12/2024

Active Pharmaceutical Ingredient: Irbesartan

Brief description of the problem

Jubilant Pharmaceuticals NV has informed the MHRA that the Patient information leaflet (PIL) in the cartons for the batch listed in the table above include an outdated PIL. These packs contain a PIL which was last revised in September 2015. The latest current approved PIL is dated August 2022

The out-of-date PIL last revised in September 2015 is missing important updated safety information, please refer to the table in Appendix 1 for information regarding updated safety information that is



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included in the most recent PIL from August 2022. The latest (current) PIL is already available on the MHRA's website:

<https://mhraproducts4853.blob.core.windows.net/docs/8fb7cf32a08140ccf7389ba6b2e9ed86006099a1>

Advice for healthcare professionals

Healthcare professionals are advised to review the information contained within this notification and take this into account when prescribing this product. When product from batch included in the table is supplied or dispensed, please ensure that patients are aware of the missing information. As the patients would not find current PIL (dated: Aug 2022) in the packs, please inform the patients that this latest (current) PIL of Irbesartan Jubilant film-coated tablets is already available on the MHRA's website:

<https://mhraproducts4853.blob.core.windows.net/docs/8fb7cf32a08140ccf7389ba6b2e9ed86006099a1>

Advice for patients

Patients should continue to take medicines from the impacted batch as prescribed by your healthcare professional. This does not affect the quality of the product. There are updated safety information in the latest patient information leaflet (PIL) which accompanies the medicine. The latest (current: last revised in Aug 2022) PIL is already available on the MHRA's website:

<https://mhraproducts4853.blob.core.windows.net/docs/8fb7cf32a08140ccf7389ba6b2e9ed86006099a1>

As per current PIL there is some missing information which is presented below:

What you need to know before you take Irbesartan Jubilant

Warnings and precautions

Talk to your doctor or pharmacist before taking Irbesartan Jubilant if

- if you develop low blood sugar levels (symptoms may include sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heart beat), particularly if you are being treated for diabetes.

You may need to have blood checks if you take:

- repaglinide (medication used for lowering blood sugar levels)

Possible side effects

- Decreased number of red blood cells (anaemia – symptoms may include tiredness, headaches, being short of breath when exercising, dizziness and looking pale), reduced number of platelets, severe allergic reactions (anaphylactic shock) and low blood sugar levels.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Further Information

For medical information enquiries please contact: safety.uk@lambda-cro.com, Telephone number: 0080089013370

For stock control enquiries please contact: JPUK.Customerservice@jubl.com, Telephone number: +4401233 552293



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Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

**Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk**



Appendix 1

Old PIL text, Dated 09/2015	Latest PIL text, Dated Aug 2022
<p>Section 2 of PIL: What you need to know before you take Irbesartan Jubilant</p> <p>Warnings and precautions Talk to your doctor or pharmacist before taking Irbesartan Jubilant and if any of the following apply to you:</p> <ul style="list-style-type: none"> ▪ if you get excessive vomiting or diarrhea. ▪ ☐ if you suffer from kidney problems. ▪ ☐ if you suffer from heart problems. ▪ ☐ if you receive Irbesartan Jubilant for diabetic kidney disease. In this case your doctor may perform regular blood tests, especially for measuring blood potassium levels in case of poor kidney function. ▪ if you are going to have an operation (surgery) or be given anaesthetics. ▪ ☐ if you are taking any of the following medicines used to treat high blood pressure: <ul style="list-style-type: none"> - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems. - aliskiren. 	<p>Section 2 of PIL: What you need to know before you take Irbesartan Jubilant</p> <p>Warnings and precautions Talk to your doctor or pharmacist before taking Irbesartan Jubilant and if any of the following apply to you:</p> <ul style="list-style-type: none"> ▪ if you get excessive vomiting or diarrhea. ▪ if you suffer from kidney problems. ▪ if you suffer from heart problems. ▪ if you receive Irbesartan Jubilant for diabetic kidney disease. In this case your doctor may perform regular blood tests, especially for measuring blood potassium levels in case of poor kidney function. ▪ <u>if you develop low blood sugar levels (symptoms may include sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heart beat), particularly if you are being treated for diabetes.</u> ▪ if you are going to have an operation (surgery) or be given anaesthetics. ▪ if you are taking any of the following medicines used to treat high blood pressure: <ul style="list-style-type: none"> ○ an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems. ○ aliskiren.
<p>Section 2 of PIL: What you need to know before you take Irbesartan Jubilant</p> <p>You may need to have blood checks if you take:</p> <ul style="list-style-type: none"> ▪ ☐ potassium supplements. ▪ ☐ salt substitutes containing potassium. ▪ ☐ potassium-sparing medicines (such as certain diuretics). ▪ ☐ medicines containing lithium. <p>If you take certain painkillers, called non-steroidal anti-inflammatory drugs, the effect of irbesartan may be reduced.</p>	<p>Section 2 of PIL: What you need to know before you take Irbesartan Jubilant</p> <p>You may need to have blood checks if you take:</p> <ul style="list-style-type: none"> ▪ potassium supplements. ▪ salt substitutes containing potassium. ▪ potassium-sparing medicines (such as certain diuretics). ▪ medicines containing lithium. ▪ <u>repaglinide (medication used for lowering blood sugar levels)</u> <p>If you take certain painkillers, called non-steroidal anti-inflammatory drugs, the effect of irbesartan may be reduced.</p>



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Old PIL text, Dated 09/2015	Latest PIL text, Dated Aug 2022
<p>Section 2 of PIL:</p> <p>What you need to know before you take Irbesartan Jubilant</p> <p>Driving and using machines</p> <p>No studies on the effects on the ability to drive and use machines have been performed. Irbesartan Jubilant is unlikely to affect your ability to drive or use machines. However, occasionally dizziness or weariness may occur during treatment of high blood pressure. If you experience these, talk to your doctor before attempting to drive or use machines.</p>	<p>Section 2 of PIL:</p> <p>What you need to know before you take Irbesartan Jubilant</p> <p>Driving and using machines</p> <p>No studies on the effects on the ability to drive and use machines have been performed. Irbesartan Jubilant is unlikely to affect your ability to drive or use machines. However, occasionally dizziness or weariness may occur during treatment of high blood pressure. If you experience these, talk to your doctor before attempting to drive or use machines.</p>
<p>Section 3 of PIL:</p> <p>How to take Irbesartan Jubilant</p> <ul style="list-style-type: none">▪ Patients with high blood pressure The usual dose is 150 mg once a day. The dose may later be increased to 300 mg once daily depending on blood pressure response.	<p>Section 3 of PIL:</p> <p>How to take Irbesartan Jubilant</p> <ul style="list-style-type: none">▪ Patients with high blood pressure <u>For 75 mg: The usual dose is 150 mg once a day (two tablets a day). The dose may later be increased to 300 mg (four tablets a day) once daily depending on blood pressure response.</u> <u>For 150 mg:</u> The usual dose is 150 mg once a day. The dose may later be increased to 300 mg <u>(two tablets a day)</u> once daily depending on blood pressure response. <u>For 300 mg: The usual dose is 150 mg once a day. The dose may later be increased to 300 mg once daily depending on blood pressure response.</u>
<p>Section 3 of PIL:</p> <p>How to take Irbesartan Jubilant</p> <ul style="list-style-type: none">▪ Patients with high blood pressure and type 2 diabetes with kidney disease In patients with high blood pressure and type 2 diabetes, 300 mg once daily is the preferred maintenance dose for the treatment of associated kidney disease.	<p>Section 3 of PIL:</p> <p>How to take Irbesartan Jubilant</p> <ul style="list-style-type: none">▪ Patients with high blood pressure and type 2 diabetes with kidney disease <u>For 75 mg:</u> In patients with high blood pressure and type 2 diabetes, 300 mg <u>(four tablets a day)</u> once daily is the preferred maintenance dose for the treatment of associated kidney disease. <u>For 150 mg: In patients with high blood pressure and type 2 diabetes, 300 mg (two tablets a day) once daily is the preferred maintenance dose for the treatment of associated kidney disease.</u>



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Old PIL text, Dated 09/2015	Latest PIL text, Dated Aug 2022
	<p><u>For 300 mg: In patients with high blood pressure and type 2 diabetes, 300 mg once daily is the preferred maintenance dose for the treatment of associated kidney disease.</u></p>
<p>Section 4 of PIL:</p> <p>Possible side effects</p> <p>Some undesirable effects have been reported since marketing of Irbesartan Jubilant. Undesirable effects where the frequency is not known are: feeling of spinning, headache, taste disturbance, ringing in the ears, muscle cramps, pain in joints and muscles, abnormal liver function, increased blood potassium levels, impaired kidney function, and inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis). Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.</p>	<p>Section 4 of PIL:</p> <p>Possible side effects</p> <p>Some undesirable effects have been reported since marketing of Irbesartan Jubilant. Undesirable effects where the frequency is not known are: feeling of spinning, headache, taste disturbance, ringing in the ears, muscle cramps, pain in joints and muscles, <u>decreased number of red blood cells (anaemia – symptoms may include tiredness, headaches, being short of breath when exercising, dizziness and looking pale), reduced number of platelets,</u> abnormal liver function, increased blood potassium levels, impaired kidney function, and inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis). <u>severe allergic reactions (anaphylactic shock) and low blood sugar levels.</u> Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.</p>
<p>Section 6 of PIL:</p> <p>Contents of the pack and other information</p> <p>What Irbesartan Jubilant contains</p> <ul style="list-style-type: none">▪ The other ingredients are lactose monohydrate, colloidal anhydrous silica (E551), microcrystalline cellulose (E460), croscarmellose sodium (E468), hypromellose (E464), pregelatinized starch, magnesium stearate (E572), titanium dioxide (E171), macrogol 4000.	<p>Section 6 of PIL:</p> <p>Contents of the pack and other information</p> <p>What Irbesartan Jubilant contains</p> <p>The other ingredients are lactose monohydrate, colloidal anhydrous silica (E551), microcrystalline cellulose (E460), croscarmellose sodium (E468), hypromellose (E464), pregelatinized starch, magnesium stearate (E572), titanium dioxide (E171), macrogol 4000. <u>Please see section 2 “Irbesartan Jubilant contains lactose”.</u></p>