Viatris Limited, Auckland. www.viatris.com.
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Lenalidomide Viatris

(lenalidomide)

Information for Healthcare Professionals (HCPs)

This document contains important safety information about Lenalidomide Viatris (lenalidomide) and advice on risk minimisation.

This booklet was developed by Viatris Ltd as part of the Lenalidomide Viatris Risk Minimisation Plan.

VIATRIS

Do not take LENALIDOMIDE VIATRIS during pregnancy.

Teratogenic Effects: LENALIDOMIDE VIATRIS (lenalidomide) is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening human birth defects. If lenalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Women should be advised to avoid pregnancy whilst taking LENALIDOMIDE VIATRIS (lenalidomide), during dose interruptions, and for 4 weeks after stopping the medication.

Reporting of suspected adverse events is important for the monitoring of the safety of all medicines.
Any adverse events which are experienced with Lenalidomide Viatris should be reported by HCPs and/or patients to:

- Centre for Adverse Reactions Monitoring (CARM) via URL:
  https://pophealth.my.site.com/carmreportnz/s/

and/or

- Viatris Care program
  Email: admin@viatriscare.co.nz
  Tel (free call): 0800 111 229

Registration to the Viatris Care program is required before prescribing or dispensing Lenalidomide Viatris. Please access at viatriscare.co.nz.

Contents

1. Lenalidomide Viatris indication

Lenalidomide Viatris is indicated for the treatment of multiple myeloma (MM), myelodysplastic syndromes (MDS), including patients with transfusion-dependent anaemia due to low- or intermediate-1 risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

For full details on Lenalidomide Viatris' indications and posology, and before prescribing, please refer to the Data Sheet, which can be found here: https://www.medsafe.govt.nz/profs/datasheet/l/LenalidomideViatriscap.pdf

2. Lenalidomide Viatris – background information

Lenalidomide Viatris is structurally related to thalidomide, a known human teratogenic substance that causes severe life-threatening birth defects. If Lenalidomide Viatris is taken during pregnancy, a teratogenic effect of Lenalidomide Viatris in humans is expected. Lenalidomide Viatris is therefore contraindicated during pregnancy. Lenalidomide Viatris is contraindicated in women of child-bearing potential unless the conditions of the Pregnancy Prevention Program, Viatris Care program, described in this booklet are carried out.

In order to ensure that the actions to minimise the risk of foetal exposure are carried out for **ALL** patients, dispensing of lenalidomide will only be allowed from pharmacists registered with the Viatris Care program. Viatris will not authorise supply of lenalidomide to pharmacists that are not registered.

3. Viatris Care program - education, therapy management, distribution control

The key information for Lenalidomide Viatris of relevance to HCPs, is contained within this booklet, including details of the:

- Viatris Care program, Pregnancy Prevention Program:
  - Educational information
  - Therapy management advice, including algorithm for evaluation of patients and implementation of Viatris Care program (User Flow) so as to avoid foetal exposure to Lenalidomide Viatris
  - Controlled distribution system: how it works
  - Relevant forms
- Safety advice and resources of relevance to all patients
- Process for reporting adverse events in patients treated with Lenalidomide Viatris.
- Contact details for the Viatris Care program.

Viatris Care program – Pregnancy Prevention Program

1. It is a requirement of the Pregnancy Prevention Program that all HCPs are registered with the Viatris Care program and that they have read and understood the relevant information before prescribing or dispensing Lenalidomide Viatris for **any** patient.
2. Algorithm for implementation of Pregnancy Prevention Program should be adhered to when prescribing Lenalidomide Viatris (see page 7).

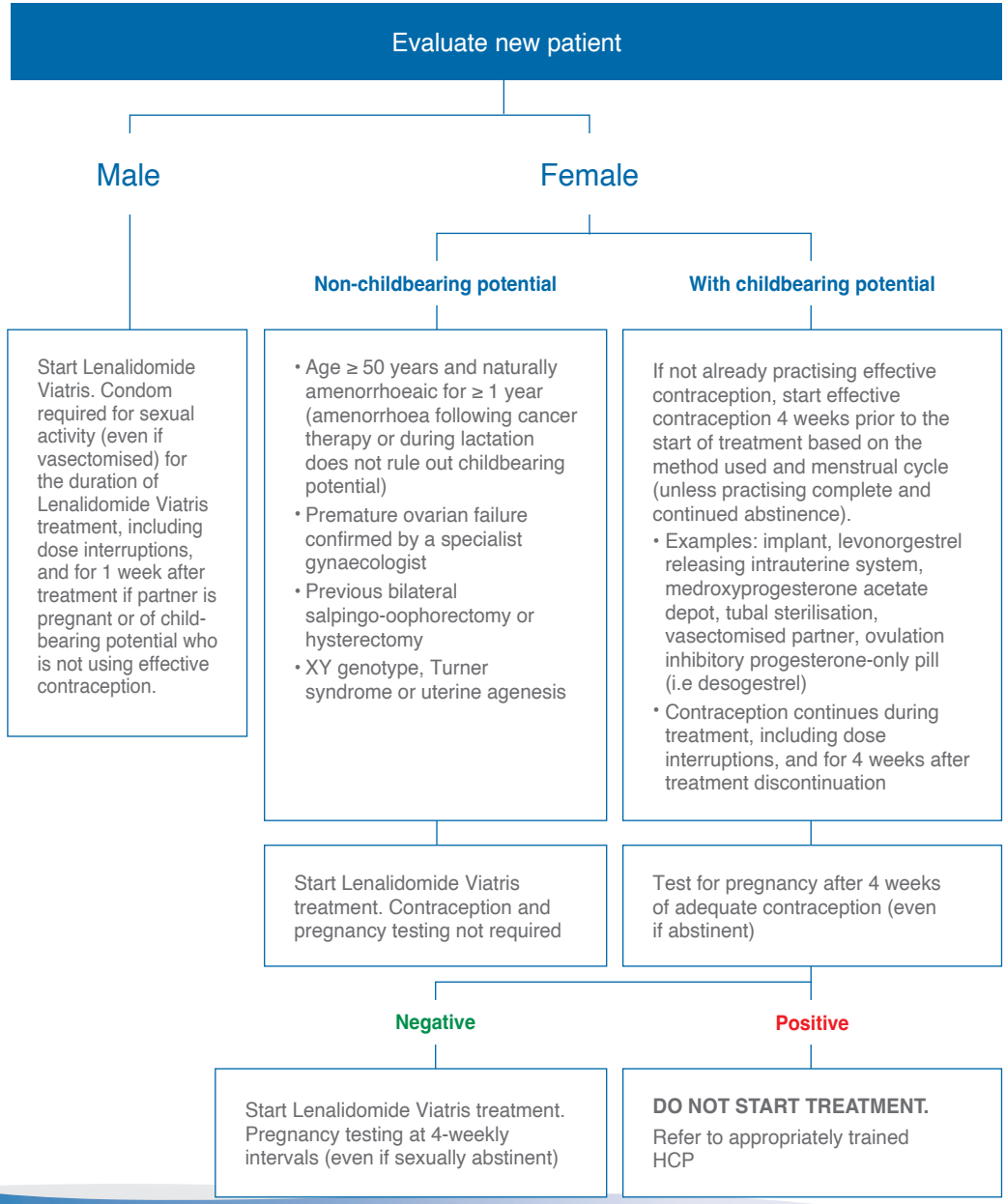
3. All Pharmacists must register with Viatris Care program to be able to order stock of Lenalidomide Viatris and dispense Lenalidomide Viatris to patients.
4. All patients should be given a Patient Booklet and Patient Card to take home – these materials remind patients of the key educational information and risks of treatment and can be found in the Resources section at www.viatriscare.co.nz.

Details about pharmacists registration in Viatris Care program as well as patient selection and prescribing lenalidomide by HCPs are presented step by step on the following page. See User Flow for Prescriber and Pharmacist, on pages 15 and 17 respectively.

In case the patients experience an AE or pregnancy while taking lenalidomide, they should report it to the prescribing physician and/or care team.

The treating physician and/or care team should complete the AE/pregnancy reporting form OR report the AE to Viatris Care program coordinators on 0800 111 229, who can complete the initial AE report on behalf of the treating physician and/or care team. Viatris or Viatris Care program Coordinator will likely follow-up any reported AEs with the treating physician and/or care team.

Algorithm for Patient Selection and Implementation of Viatris Care program (Pregnancy Prevention Program)



4. Patient and HCP education

All patients must sign a patient informed consent form (Patient Consent to Treatment and Health Info Collection), confirming their awareness of the risks of treatment, particularly of the risks associated with foetal exposure and their agreement to adhere to the requirements of the program. An example of the patient informed consent form is provided in the in the Resources section at www.viatriscare.co.nz.

All patients should be given a copy of the Patient Booklet to take home. The booklet has separate sections containing information for women of childbearing potential, women of non-childbearing potential and men, as well as a section describing safety information relevant to all patients.

All HCPs involved in the prescribing of Lenalidomide Viatris must:

i. Confirm that they have read and understand the HCPs Information Booklet (this document),
ii. Consult the HCP algorithm for patient selection & Viatris Care program implementation provided in this booklet before prescribing lenalidomide to patients
iii. Conduct discussion with the patient about the Pregnancy Prevention program
iv. Register in the Viatris Care program
v. Register patient in the Viatris Care program
vi. Write prescription and hand them over, together with the Patient booklet, Patient card, Patient Consent to Treatment and Health Info Collection form and letter to GP.

5. Therapeutic management and advice to avoid foetal exposure

Women of non-childbearing potential

Women in the following groups are considered not to have childbearing potential and do not need to undergo pregnancy testing or receive contraceptive advice.

- Age ≥ 50 years and naturally amenorrhoeic for ≥ 1 year. Please note amenorrhea following cancer therapy or during lactation does not rule out child-bearing potential
- Premature ovarian failure confirmed by a specialist gynaecologist
- Previous bilateral salpingo-oophorectomy, or hysterectomy
- XY genotype, Turner syndrome, uterine agenesis.

Treating physicians are advised to refer their patient for a gynecological opinion if at all unsure as to whether a woman meets the criteria for being of non-childbearing potential.

Women of childbearing potential

In view of the expected teratogenic risk of Lenalidomide Viatris, foetal exposure should be avoided.

Women of childbearing potential (even if they have amenorrhea) must:

- Use one effective method of contraception (see following page) for 4 weeks before therapy, during therapy, and until 4 weeks after Lenalidomide Viatris therapy, and even in case of dose interruption

or

- Commit to absolute and continuous sexual abstinence

and

- Have a medically supervised negative pregnancy test (with a minimum sensitivity of 25 mIU/mL) once established on contraception for 4 weeks, at 4-weekly intervals during therapy (this includes interruptions) and 4 weeks after the end of therapy (unless confirmed tubal sterilisation). This also includes those women of childbearing potential who confirm absolute and continued sexual abstinence.

Best practice is to conduct the pregnancy test and prescribe on the same day. There must be **no more than 7 days** between the last negative pregnancy test and the dispensing. For optimal stock management, it is advisable for the negative pregnancy test to remain valid for at least 3 days to allow the pharmacist to order the necessary stock.

If not established on effective contraception, the patient must be referred to an appropriately trained HCP for contraceptive advice so that contraception can be initiated.

The following can be considered to be examples of suitable methods of contraception:

- Implant
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot
- Tubal sterilisation
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
- Ovulation inhibitory progesterone-only pills (i.e. desogestrel).

Your patient should be advised that, if a pregnancy occurs whilst she is receiving Lenalidomide Viatris, she must immediately stop treatment and inform her physician.

In the event of the treated female patient falling pregnant,

Stop treatment

Refer the patient to a physician specialised or experienced in teratology for evaluation and advice.

Notify the Viatris Care program team immediately of all such occurrences at:
Viatris Care program
Email: admin@viatriscare.co.nz
Tel (free call): 0800 111 229.

Please also complete the Pregnancy Reporting form downloaded from www.viatriscare.co.nz under Resources. For assistance on completion of the form, please contact Viatris Care program.

The positive pregnancy must also be reported in the patient's record.

Men

In view of the expected teratogenic risk of Lenalidomide Viatris, foetal exposure should be avoided.

Pharmacokinetic data has demonstrated that Lenalidomide Viatris is present in human semen at extremely low levels during treatment and is undetectable in human semen 3 days after stopping the drug in the healthy subject.

Sperm donation

Patients should also not donate sperm during therapy (including during dose interruptions) or for at least 7 days following discontinuation of Lenalidomide Viatris.

As a precaution, all male patients taking Lenalidomide Viatris must meet the following conditions:

- If their partner is pregnant or of childbearing potential and not using effective contraception, male patients should use condoms throughout the duration of treatment, during dose interruption and for 1 week after cessation of treatment, even if the male patient has undergone a vasectomy.
- **If pregnancy occurs in a partner of a male patient whilst he is taking Lenalidomide Viatris or shortly after he has stopped taking Lenalidomide Viatris, he should inform his treating doctor immediately. The partner should inform her physician immediately. It is recommended that she be referred to a physician specialised in teratology for evaluation and advice.**

Blood donation

All patients receiving Lenalidomide Viatris should not donate blood during treatment and for 1 week after cessation of treatment with Lenalidomide Viatris.

6. Prescribing Lenalidomide Viatris

Maximum prescription lengths

You may prescribe a maximum of four weeks of therapy for women of childbearing potential, or twelve weeks of therapy for all other patients. Lenalidomide Viatris treatment should be supervised by a physician experienced in the use of anti-cancer therapies and a full understanding of the risks of Lenalidomide Viatris therapy and monitoring requirements.

Initial prescription

Before issuing the initial prescription, you must:

- Counsel the patient on the safe use of Lenalidomide Viatris in accordance with the measures described in this booklet and the Data Sheet (DS)
- Counsel the patient and get them to sign the Patient Consent to Lenalidomide Viatris Treatment and Patient Health Information Collection and Storage Form, to document that they have received and understood this information
- Provide the patient with a Patient Booklet and Patient Card

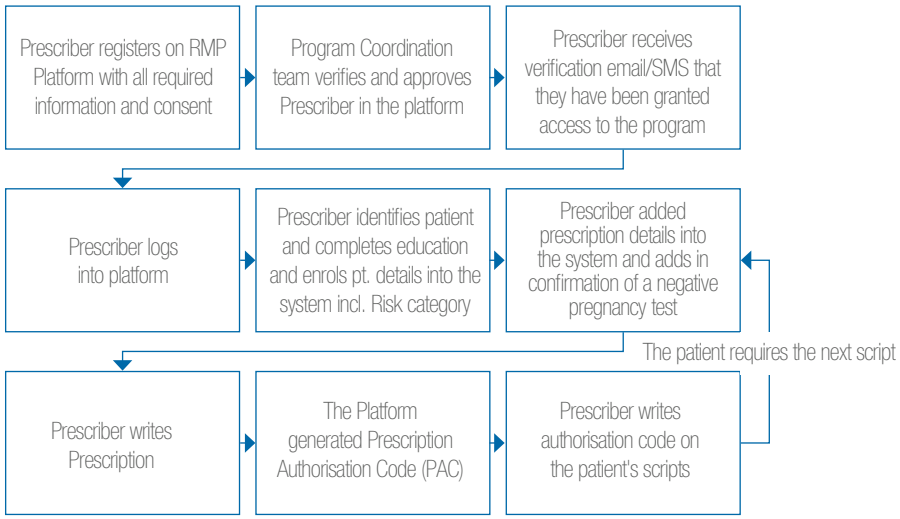
- Register the patient's details into the Viatris Care program including their risk category. A unique system generated ID will be assigned for each patient record.
    - Patient initials, date of birth and diagnosis
    - Patient category (women of childbearing potential, women of non-childbearing potential, or male).
    - Prescriber name and declaration that the patient has received counselling on the safe use of Lenalidomide Viatris
    - For women of childbearing potential, the pregnancy test date and result
    - Patient's prescription details
- Write the Prescription Authorisation Code (PAC) on the prescription that is provided to the patient

On submission of the prescription information, the system auto-generates a PAC that is valid for 7 days for childbearing women and 28 days for non-childbearing women or men. The PAC will be generated only when the prescriber registration has been successfully completed, the patient's record is complete and for female patients with childbearing potential, a negative pregnancy test result is entered.

Repeat of subsequent prescriptions

The patient must return to the initial prescriber for every repeat prescription of Lenalidomide Viatris. If a patient is transferred or consulted by another prescriber, the initial prescriber must remind them to contact Viatris or register via website or phone, see Section 10 Contact Details on page 27.
Once registered, the prescriber is able to access the Lenalidomide Viatris Resources, see User Flow: Prescriber diagram (page 15).

User Flow: Prescriber



7. Controlled distribution system

It is a requirement of the Pregnancy Prevention Program that pharmacists wishing to purchase and dispense Lenalidomide Viatris are registered with Viatris Care program.

In order to be registered, the pharmacist must:

- complete their details on Viatris Care program
- confirm that they have read and understood the Healthcare Professional's (HCP's) Information Booklet (this document).

Access to the Viatris Care program is granted following verification and approval by the Program Coordination team.

Dispensing of Lenalidomide Viatris will only be allowed from pharmacists registered on Viatris Care program. Non-registered pharmacists will not have access to Viatris Care program to view patient information.

The dispensing pharmacist must:

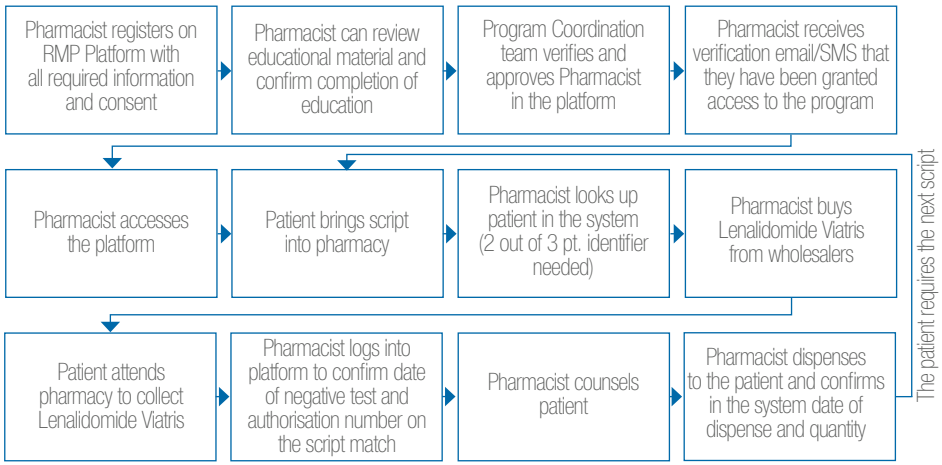
- Retrieve the patients' record using the PAC, otherwise, a search can be performed using the patient's full name and date of birth.
- Check maximum duration of treatment prescribed according to the approved indications dosing regimens
  - 4 weeks treatment for women with childbearing potential
  - 12 weeks treatment for men and women without childbearing potential
- Check that the Prescription Authorisation Code matches in Viatris Care program and on the prescription
- Document the medication dispensed date in the patient's record

For women of childbearing potential, prescriptions for Lenalidomide Viatris should be limited to 4 weeks of treatment and continuation of treatment requires a new prescription.

- Check dispensing is taking place **7 days or less** from the date of the last negative pregnancy test.
- Best practice is to conduct the pregnancy test and prescribe on the same day. There must be **no more than 7 days** between the last negative pregnancy test and the dispensing. For optimal stock management, it is advisable for the negative pregnancy test to remain valid for at least 3 days to allow the pharmacist to order the necessary stock.
- For males and women of non-childbearing potential, prescriptions of Lenalidomide Viatris should be limited to 12 weeks and continuation of treatment requires a new prescription.

It is critical that Authorisations within Viatris Care program are completed accurately.

User Flow: Pharmacist



8. Safety advice relevant to all patients

The following section contains advice to HCPs about how to minimise the risk of the principal adverse events associated with the use of Lenalidomide Viatris. For a full list of the adverse events that may be associated with its use, please refer to the Data Sheet.

8.1. Myelosuppression

Neutropenia and thrombocytopenia are the major dose-limiting toxicities of treatment with Lenalidomide Viatris. The combination of Lenalidomide Viatris with dexamethasone in multiple myeloma patients is associated with an incidence of Grade 4 neutropenia of 4.8% compared with 0.6% in placebo/dexamethasone-treated patients.

Episodes of Grade 4 febrile neutropenia were observed infrequently – occurring in 0.6% in Lenalidomide Viatris/dexamethasone-treated patients compared to 0.0% in placebo/dexamethasone-treated patients.

The combination of Lenalidomide Viatris with dexamethasone in multiple myeloma patients is associated with a higher incidence of Grade 3 and Grade 4 thrombocytopenia (10.8% and 1.4%, respectively), in lenalidomide/dexamethasone-treated patients compared to 5.4% and 0.9% in placebo/dexamethasone-treated patients.

The frequency of blood monitoring depends on various factors (e.g. indication, use of combination drug therapy, number of treatment cycles). Please refer to the Data Sheet for full details. A dose reduction may be required. In case of neutropenia, the physician should consider the use of growth factors in patient management. Patients should be advised to promptly report febrile episodes. Co-administration of lenalidomide with other myelosuppressive agents should be undertaken with caution.

8.1.1. Use in multiple myeloma

Treatment with Lenalidomide Viatris must not be started if the baseline Absolute Neutrophil Count (ANC) and/or platelet count are below a certain level, and these differ depending on various factors. Please refer to the Data Sheet for full details.

Recommended dosage adjustments during treatment and restart of treatment with Lenalidomide Viatris in multiple myeloma

The recommended starting dose and dosage adjustments for multiple myeloma differ depending on various factors (e.g. eligibility for autologous stem cell transplantation, use of combination drug therapy). Please refer to the Data Sheet for full details.

Dosing is continued or modified based upon clinical and laboratory findings. Prescribing physicians should carefully evaluate which dose of dexamethasone to use, taking into account the condition and disease status of the patient.

In the case of neutropenia, the physician should consider the use of growth factors in patient management.

8.1.2. Use in myelodysplastic syndromes

Lenalidomide Viatris treatment must not be started if the Absolute Neutrophil Count (ANC) < 0.5 x 10^9/L and/or platelet count < 50 x 10^9/L.

The recommended starting dose of lenalidomide is 10 mg orally once daily on days 1-21 of repeated 28-day cycles. Dosing is continued or modified based upon clinical and laboratory findings.

Recommended dose adjustments during treatment and restart of treatment

The recommended dose adjustments for myelodysplastic syndromes are

divided into 2 sets – for within the first 4 weeks of treatment, and after the first 4 weeks of treatment. Please refer to the Data Sheet for full details.

8.2. Patients who experience other toxicities

For other Grade 3 or 4 toxicities judged to be related to lenalidomide, stop treatment and restart at next lower dose level when toxicity has resolved to ≤ Grade 2 depending on the physician's discretion.

Lenalidomide interruption or discontinuation should be considered for Grade 2 or 3 skin rash. Lenalidomide must be discontinued for angioedema, anaphylaxis, Grade 4 rash exfoliative or bullous rash, or if Stevens-Johnson syndrome or toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS) is suspected, and should not be resumed following discontinuation from these reactions.

8.3. Venous and arterial thromboembolism

In patients with multiple myeloma, the combination of Lenalidomide Viatris and dexamethasone is associated with an increased risk of venous and arterial thromboembolic events (mainly deep vein thrombosis, pulmonary embolism, myocardial infarctions and cerebrovascular events). In patients with myelodysplastic syndromes, treatment with lenalidomide monotherapy was also associated with a risk of venous thromboembolism (predominantly deep vein thrombosis and pulmonary embolism), but to a lesser extent than in patients with multiple myeloma. Concomitant administration of erythropoietic agents and previous history of deep vein thrombosis may increase the thrombotic risk in patients. Action should be taken to try to minimise all modifiable risk factors for thromboembolic events (e.g. smoking cessation, control of hypertension and hyperlipidaemia). Patients with known risk factors for thromboembolism should be closely monitored.

Prophylactic antithrombotic medications, such as low molecular weight heparins or warfarin are recommended, especially in patients with additional thrombotic risk factors. The decision to take antithrombotic prophylactic measures should be made after careful assessment of an individual patient's underlying risk factors. If the patient experiences any thromboembolic events, treatment must be discontinued and standard anticoagulation therapy started. Once the patient has been stabilised on the anticoagulation treatment and any complications of the thromboembolic event have been managed, the Lenalidomide Viatris treatment may be restarted at the original dose, dependent upon a benefit-risk assessment. The patient should continue anticoagulation therapy during the course of Lenalidomide Viatris treatment.

8.4. Use in renal impairment

Lenalidomide Viatris is substantially excreted by the kidney and therefore care should be taken in dose selection. Regular monitoring of renal function is advised. It is important to dose adjust patients with renal impairment in order to avoid plasma levels which may increase the risk for higher haematological side effects or hepatotoxicity. Please refer to the Data Sheet for full details.

8.5. Use in hepatic impairment

Lenalidomide Viatris has not formally been studied in patients with impaired hepatic function and there are no specific dose recommendations.

8.6. Thyroid function

Cases of hypothyroidism and hyperthyroidism have been reported. Optimal control of comorbid conditions that can affect thyroid function is recommended before start of treatment. Baseline and ongoing monitoring of thyroid function is recommended.

8.7. Peripheral neuropathy

Lenalidomide Viatris is structurally related to thalidomide, which is known to induce severe peripheral neuropathy. At this time, the neurotoxic potential of Lenalidomide Viatris associated with long-term use cannot be ruled out.

8.8 Tumour lysis syndrome (TLS) and tumour flare reaction (TFR)

Cases of TLS and TFR including fatal cases have been reported. Fatal instances of TLS have been reported during treatment with lenalidomide. Patients at risk of TLS and TFR are those with high tumour burden prior to treatment. Caution should be practiced when introducing these patients to lenalidomide. These patients should be monitored closely, especially during the first cycle or dose-escalation, and appropriate precautions taken. There have been rare reports of TLS in patients with multiple myeloma treated with lenalidomide, and no reports in patients with myelodysplastic syndrome treated with lenalidomide.

8.9. Allergic reactions

Cases of allergic reaction/hypersensitivity reactions have been reported. Patients with a prior history of Grade 4 rash associated with thalidomide treatment should not receive lenalidomide. Patients who had previous allergic reactions while treated with thalidomide should be monitored closely, as a possible cross-reaction between Lenalidomide Viatris and thalidomide has been reported in the literature.

8.10. Severe skin reactions

Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported. Lenalidomide Viatris must be discontinued for exfoliative or bullous rash, or if SJS or TEN is suspected, and should not be resumed following discontinuation for these reactions. Interruption or discontinuation of Lenalidomide Viatris should be considered for other forms of skin reaction depending on severity. Patients with a history of severe rash associated with thalidomide treatment should not receive Lenalidomide Viatris; more information can be found in the Data Sheet and in Section 8.2.

8.11. Second primary malignancies (SPM)

An increase of SPM has been observed in clinical trials in previously treated myeloma patients receiving lenalidomide/dexamethasone (3.98 per 100 patient -years) compared to placebo/dexamethasone (1.38 per 100 patient-years). Non-invasive SPM comprise basal cell or squamous cell skin cancers. Most of the invasive SPMs were solid tumour malignancies.

Among invasive SPMs, in clinical trials of newly diagnosed multiple myeloma patients eligible for ASCT, an increased incidence rate of haematologic SPM (most notably AML, MDS and B-cell malignancies [including Hodgkin's lymphoma]) has been observed in patients receiving lenalidomide maintenance immediately following high-dose melphalan/autologous stem-cell transplantation (1.31 per 100 person-years) compared with patients who received placebo (0.58 per 100 person-years).

The risk of occurrence of SPM must be taken into account before initiating treatment with Lenalidomide Viatris. Physicians should carefully evaluate patients before and during treatment using standard cancer screening for occurrence of SPM and institute treatment as indicated.

8.12. Increased mortality in Chronic Lymphocytic Leukaemia (CLL)

In a prospective randomized (1:1) clinical trial in the first line treatment of patients with CLL, single agent lenalidomide therapy was associated with an increased risk of death as compared to single agent chlorambucil. Lenalidomide is not recommended for use in CLL outside of controlled clinical trials.

8.13. Blood donation

Patients should not donate blood during therapy (including during dose interruptions), or for 1 week following discontinuation of lenalidomide.
In New Zealand, patients with some cancers may be permanently excluded from donating blood.

8.14. Sperm donation

Patients should not donate sperm during therapy (including during dose interruptions) or for at least 7 days following discontinuation of Lenalidomide Viatris.

8.15. Safety and off-label use

Please note that the posology, adverse event profile and recommendations outlined above, particularly in respect of neutropenia and thrombocytopenia, relate to the use of Lenalidomide Viatris within its licensed indication. There is currently insufficient evidence regarding safety and efficacy in any other indication.

Lenalidomide Viatris must always be used according to the Pregnancy Prevention Program described in this booklet – these precautions must be followed, irrespective of the treatment setting, including the indication for treatment.

It is essential that the patient's diagnosis is entered on their record in the Viatris Care program - this will allow an assessment of the clinical usage of Lenalidomide Viatris, which is important for ongoing monitoring of safety, and to ensure that Lenalidomide Viatris is supplied for the treatment of eligible patients.

8.16. Disposal of unwanted medicine

Patients must be advised never to give Lenalidomide Viatris to another person and to return any unused capsules to their pharmacist at the end of the treatment.

9. Targeted adverse reaction follow-up forms

Specific adverse reaction follow-up forms have been developed for identified risks, which can be downloaded from Viatris Care program under Resources. For assistance, please contact the Viatris Care program Team.
Contact (email): admin@viatriscare.co.nz or (Free call) 0800 111 229

- Teratogenicity (Pregnancy targeted follow-up forms)
- Serious infection due to neutropenia
- Second primary malignancies (SPM)
- Tumour Flare Reaction (TFR)
- Cardiac failure
- Cardiac arrhythmias
- Ischaemic heart disease (including myocardial infarction)
- Off-label use.

10. Contact details

Viatris Care program - Pregnancy Prevention Program:
Tel: 0800 111 229
Email: admin@viatriscare.co.nz
URL Access: www.viatriscare.co.nz

Do not take LENALIDOMIDE VIATRIS during pregnancy.

Teratogenic Effects: LENALIDOMIDE VIATRIS (lenalidomide) is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening human birth defects. If lenalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Women should be advised to avoid pregnancy whilst taking LENALIDOMIDE VIATRIS (lenalidomide), during dose interruptions, and for 4 weeks after stopping the medication.

For full details on Lenalidomide Viatris' indications and posology, and before prescribing, please refer to the Data Sheet, which can be found here:

https://www.medsafe.govt.nz/profs/datasheet/l/LenalidomideViatriscap.pdf

Lenalidomide Viatris (lenalidomide) 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg & 25 mg. Prescription Medicine. Indication: for the treatment of multiple myeloma (MM) & myelodysplastic syndromes (MDS) in adults. Contraindications: Hypersensitivity to lenalidomide or any of the excipients; pregnant women; women of child-bearing potential unless all conditions of the pregnancy prevention program are satisfied. Precautions: female patient or female partner of a male patient considered of child-bearing potential must comply with contraception requirements, have a negative pregnancy test within 7 days of dispensing; no blood or sperm donation for the duration of treatment and 1 week following discontinuation; minimise & monitor patients with: known risk factors for thromboembolism, cardiopulmonary disease, neutropenia & thrombocytopenia, thyroid conditions, peripheral neuropathy, prior history of Grade 4 rash associated with thalidomide should not receive lenalidomide; use in hepatic & renal impairment. Adverse Effects: Tumour lysis syndrome & tumour flare reaction; allergic reactions/ serious skin reactions such as DRESS; hypothyroidism; Venous thromboembolic events; neutropenia; thrombocytopenia; anaemia; pulmonary hypertension; myocardial infarction; diarrhoea; nausea; constipation; decreased appetite; peripheral oedema; fatigue; back pain; muscle spasms; insomnia. Dosage & Administration: for NDMM ineligible for ASCT or previously treated MM: usually 25 mg once daily on Days 1-21 of repeated 28-day cycle; for NDMM post ASCT: usually 10 mg once daily continuously for 3 months before dose adjustments; For MDS: usually 10 mg once daily on Days 1-21 of repeated 28-day cycle. Dosing for all indications should be monitored and adjusted accordingly, see data sheet for further information. As teratogenic effects cannot be ruled out, mandatory registration with Viatris Care program is required for HCPs and patients. Regular pregnancy tests are required for child-bearing women. Before prescribing, please refer to the full data sheet, available from www.medsafe.govt.nz. Viatris Limited, Auckland.

TAPS DA 2303MM-0410.

Notes