LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Davunfite
(pomalidomide)

SE/H/2470/01-04/DC

This module reflects the scientific discussion for the approval of Davunfite. The procedure was finalised on 2024-11-20. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, a marketing authorisation has been granted for Davunfite, 1 mg, 2 mg, 3 mg, 4 mg, Capsule, hard.

The active substance is pomalidomide. A comprehensive description of the indication and posology is given in the SmPC.

For recommendations to the marketing authorisation not falling under Article 21a/22a/22 of Directive 2001/83/EC and conditions to the marketing authorisation pursuant to Article 21a/22a/ 22 of Directive 2001/83/EC to the marketing authorisation, please see section VI.

The application for Davunfite, 1 mg, 2 mg, 3 mg, 4 mg, Capsule, hard, is a generic application submitted according to Article 10(1) of Directive 2001/83/EC. The applicant applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and FR as concerned member state (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Imnovid, 1 mg, capsule, hard, authorised in Union since 2013, with Bristol-Myers Squibb Pharma EEIG as marketing authorisation holder.

The reference product used in the bioequivalence study is Imnovid, 4 mg, capsule, hard from Germany with Bristol-Myers Squibb Pharma EEIG as marketing authorisation holder.

Potential similarity with orphan medicinal products
The applicant has provided a similarity report (Module 1.7.1) due to potential similarity with authorised orphan medicinal product(s) under market exclusivity.

Conclusion
Having considered the arguments presented by the applicant and with reference to Article 8 of Regulation (EC) No 141/2000, of Davunfite are considered not similar (as defined in Article 3 of Commission Regulation (EC) No. 847/2000) to the authorised orphan medicinal products listed in the table below.

Therefore, with reference to Article 8 of Regulation (EC) No. 141/2000, the existence of any market exclusivity for these products in the treatment of treatment of multiple myeloma, does not prevent the granting of the marketing authorisation of Davunfite. This finding is without prejudice to the outcome of the scientific assessment of the marketing authorisation application.

Table: Similarity assessment

Medicinal product under evaluation	**Authorised Orphan medicinal product**	**Final conclusion**
Davunfite	Ninlaro (Ixazomib)	NOT SIMILAR based on mechanism of action and principal molecular structure
	Carvykti (ciltacabtagene autoleucel)	NOT SIMILAR based on mechanism of action and principal molecular structure

Medicinal product under evaluation	Authorised Orphan medicinal product	Final conclusion
	Abecma (idecabtagene vicleucel)	NOT SIMILAR based on mechanism of action and principal molecular structure
	Kyprolis (Carfilzomib)	NOT SIMILAR based on mechanism of action and principal molecular structure
	Blenrep (belantamab mafodotin)	NOT SIMILAR based on mechanism of action and principal molecular structure
	Farydak (Panobinostat)	NOT SIMILAR based on mechanism of action and principal molecular structure
	Darzalex (Daratumumab)	NOT SIMILAR based on mechanism of action and principal molecular structure
	Talvey (Talquetamab)	NOT SIMILAR based on mechanism of action and principal molecular structure

II. QUALITY ASPECTS

II.1 Drug Substance

The structure of the drug substance has been adequately proven and its physico-chemical properties are sufficiently described.

The manufacture of the drug substance has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The drug substance specification includes relevant tests and the limits for impurities and degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies confirm the retest period.

II.2 Medicinal Product

The medicinal product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

The manufacturing process has been sufficiently described and critical steps identified.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies have been performed and data presented support the shelf life and special precautions for storage claimed in the Summary of Product Characteristics, sections 6.3 and 6.4.

III. NON-CLINICAL ASPECTS

Pharmacology/Pharmacokinetics/Toxicology
Pharmacodynamic, pharmacokinetic and toxicological properties of pomalidomide are well known. As pomalidomide is a widely used, well-known active substance, no further studies are required, nor does the applicant provide any. Overview based on literature review is, thus, appropriate.

Environmental Risk Assessment (ERA)
Since Davunfite is a generic product, they will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

There are no objections to approval of Sulabcote and others from a non-clinical point of view.

IV. CLINICAL ASPECTS

Pharmacokinetics
To support the marketing authorisation application the applicant has conducted one single-dose bioequivalence study comparing Sulabcote (Pomalidomide) with the reference product Imnovid.

Pharmacokinetic properties of the active substance
Absorption:
Pomalidomide is absorbed with a maximum plasma concentration (C_{max}) occurring between 2 and 3 hours and is at least 73% absorbed following administration of single oral dose.

Coadministration with a high-fat and high-calorie meal slows the rate of absorption, decreasing mean plasma C_{max} by approximately 27%, but has minimal effect on the overall extent of absorption with an 8% decrease in mean AUC. Therefore, pomalidomide can be administered without regard to food intake.

Linearity:
The systemic exposure (AUC) of pomalidomide increases in an approximately linear and dose proportional manner.

Elimination:
Pomalidomide is eliminated with a median plasma half-life of approximately 9.5 hours in healthy subjects and approximately 7.5 hours in patients with multiple myeloma.

Study BE-2181-22
Methods
This was a single-dose, two-way crossover study conducted in 40 healthy volunteers (36 completed), comparing Pomalidomide, 4 mg, capsule with Imnovid, 4 mg, hard capsule under fasting conditions. Blood samples for concentration analysis were collected pre-dose and up to 48 hours post-dose. Plasma concentrations of pomalidomide were determined with a LC-MS/MS method. Analysis of variance (ANOVA) was performed on the log-transformed data for AUC_{0-t} and C_{max}. The study was conducted between 22/MAY/23 and 01/JUN/23.

Results
The results from the pharmacokinetic and statistical analysis are presented in Table 1 below.

Table 1. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} median, range) for pomalidomide, n=36.

Treatment	AUC_{0-t} ng*h/ml	C_{max} ng/ml	t_{max} h
Test	**722.62 ± 167.383**	**74.54 ± 13.062**	**2.00 (0.67-4.50)**
Reference	**698.80 ± 157.647**	**69.00 ± 11.931**	**2.26 (0.67-4.52)**
***Ratio (90% CI)**	**103.18 (100.14-106.31)**	**108.09 (104.37-111.95)**	**-**

AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
C_{max} maximum plasma concentration
t_{max} time for maximum plasma concentration

**calculated based on ln-transformed data*

For AUC_{0-t} and C_{max} the 90% confidence interval for the ratio of the test and reference products fell within the conventional acceptance range of 80.00-125.00%.

A biowaiver was sought for the additional strengths of 1 mg, 2 mg and 3 mg.

Discussion and overall conclusion
The bioequivalence study and its statistical evaluation were in accordance with accepted standards for bioequivalence testing, as stated in the Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/Corr). The bioanalytical method was adequately validated.

Based on the submitted bioequivalence study, Sulabcote is considered bioequivalent with Imnovid.

Absence of studies with the additional strengths of 1 mg, 2 mg and 3 mg is acceptable, as all conditions for biowaiver for additional strength(s), as described in the Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/Corr) are fulfilled and since the pharmacokinetics of pomalidomide is linear between 1 mg and 4 mg.

Pharmacodynamics/Clinical efficacy/Clinical safety
No new studies on pharmacodynamics, clinical efficacy or clinical safety have been submitted. As bioequivalence with the originator product has been adequately demonstrated, additional data is not deemed necessary.

Risk Management Plan
SE/H/2470/01-04/DC – Davunfite

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Davunfite.

Part II Safety specification
The safety concerns are summarised below. The safety concerns are aligned with those of the originator, which is endorsed.

Summary of safety concerns	
Important identified risks	• Teratogenicity • Severe infection due to neutropenia and pancytopenia • Thrombocytopenia and bleeding • Cardiac failure • Non-Melanoma skin cancer
Important potential risks	• Other Second primary malignancies • Cardiac arrhythmia
Missing information	None

Part III.1 Routine pharmacovigilance activities
As part of routine pharmacovigilance activities beyond adverse reactions reporting and signal detection, the below listed adverse event follow-up questionnaires are proposed:

Important Identified or Potential Risk	Follow up Form Title
Teratogenicity	Event-Specific Questionnaire for HCP – Pregnancy Background (Patient or Partner of Patient) Event-Specific Questionnaire for Patient or Male Patient of Pregnant Partner – Pregnancy Background Event-Specific Questionnaire for HCP – Pregnancy Follow-up (Patient or Partner of Patient) Event-Specific Questionnaire for HCP – Pregnancy outcome (Patient or Partner of Patient) Event-Specific Questionnaire for Patient or Male Patient of Pregnant Partner – Pregnancy outcome Event-Specific Questionnaire for Primary Care Physician or Paediatrician – Infant Follow-up
Severe Infection due to Neutropenia and Pancytopenia	Neutropenia
Thrombocytopenia and Bleeding	Thrombocytopenia / Bleeding
Cardiac Failure	Cardiac Failure
Non-melanoma Skin Cancer	Second Primary Malignancies
Other Second Primary Malignancies	Second Primary Malignancies
Cardiac Arrhythmia	Cardiac Arrhythmia and ECG Changes

The forms are provided in Annex 4.

The proposed follow-up questionnaires comply with those of the innovator, which is endorsed.

Part III.2 Additional pharmacovigilance activities
Expedited Reporting and Follow-up of Pregnancy:
The pregnancy capture and follow-up procedure is detailed in this section of the RMP. The PPP aims to minimise the risks of teratogenicity by ensuring HCPs and patients are fully informed of and understand the risks of teratogenicity prior to starting their pomalidomide treatment.

Part III.3 Summary table of Additional pharmacovigilance activities

Study status	Summary of Objectives	Safety Concern Addressed	Milestones	Due dates
Pregnancy Prevention Programme	Monitoring of implementation of the PPP	Teratogenicity	Routine PSURs in line with DLP of the latest EURD list.	Data will be reviewed on an ongoing basis as part of signal detection and reported within PSURs in line with EURD list.

Albeit the fact that the PSUR requirement is unapplicable for generic pomalidomide products - according to the current EURD list - reference to PSUR in line with DLP of the EURD list has been included in the RMP for harmonisation purposes. This is endorsed.

Part V Risk minimisation measures

Table Part V.3: Summary table of pharmacovigilance activities and risk minimisation activities by safety concern

Safety concern	Risk minimisation measures	Pharmacovigilance activities
Important Identified Risks		
Teratogenicity	**Routine risk minimisation measures** SmPC Section 4.3 and 4.4 PL The PL warns of the potential teratogenic effects of pomalidomide and the need to avoid pregnancy. **Additional risk minimisation measures** Pregnancy Prevention Programme.	**Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection** AE follow up forms for adverse reaction. **Additional pharmacovigilance activities** None

	-Educational Healthcare Professional's Kit -Educational Brochures for patients -Patient Card or equivalent tool -Risk Awareness Forms Monitoring of implementation and compliance of the PPP	
Severe Infection due to Neutropenia and Pancytopenia	**Routine risk minimisation measures** SmPC Section 4.2, 4.4 and 4.8 PL Advice to patients including a warning that the doctor is advised to check if the patient has ever had hepatitis B infection prior to starting pomalidomide treatment. **Additional risk minimisation measures** None	**Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection** Event specific questionnaire for the collection of the AE and follow-up **Additional pharmacovigilance activities** None
Thrombocytopenia and bleeding	**Routine risk minimisation measures** SmPC Sections 4.2, 4.4 and 4.8 PL The PL warns that pomalidomide may cause bleeding or bruising without a cause, and lists bleeding within the skull, nosebleeds and bleeding from the bowels or stomach as possible side effects. **Additional risk minimisation measures** Educational Brochures for patients HCP Educational Materials	**Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection** Event specific questionnaire for the collection of the AE and follow-up **Additional pharmacovigilance activities** None
Cardiac failure	**Routine risk minimisation measures** SmPC Sections 4.4 and 4.8 PL A warning regarding heart failure is included in the PL. **Additional risk minimisation measures** HCP Educational Materials	**Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection** Event specific questionnaire for the collection of the AE and follow-up **Additional pharmacovigilance activities** None

Non-melanoma skin cancer	**Routine risk minimisation measures** SmPC Sections 4.4 and 4.8 PL A warning regarding BCC and SCC is included in the PL **Additional risk minimisation measures** None	**Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection** Event specific questionnaire for the collection of the AE and follow-up. **Additional pharmacovigilance activities** None
Important potential Risks		
Other Second primary malignancies	**Routine risk minimisation measures** SmPC Section 4.4 and 5.3 PL A warning regarding BCC and SCC is included in the PL **Additional risk minimisation measures** None	**Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection** Event specific questionnaire for the collection of the AE and follow-up. **Additional pharmacovigilance activities** None
Cardiac arrhythmia	**Routine risk minimisation measures** SmPC Section 4.8 PL AF listed in PL **Additional risk minimisation measures** None	**Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection** Event specific questionnaire for the collection of the AE and follow-up. **Additional pharmacovigilance activities** None

The proposed risk minimisation measures – both routine and additional - are considered adequate and properly aligned with those of the originator RMP.

Part VI Summary of the RMP
The applicant has adequately summarised the RMP.

Conclusion RMP assessment
The submitted Risk Management Plan, **version 0.4, dated 18 Nov 2024**, is considered acceptable.

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:
- At the request of the RMS;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or

as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time, but via different procedures.

V. USER CONSULTATION

A full user test report for the package leaflet of another pomalomide generic product, ie. *Pomalidomide Teva hard capsules* has been assessed and accepted. The language used for the purpose of user testing the PL was English.

Moreover, a bridging report has been provided, comparing the parent PL (*Pomalidomide Teva hard capsules)* and the daughter PL (*Davunfite*). The bridging report is found acceptable.

In conclusion, the user testing requirement is considered fulfilled.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the generic product, Davunfite, is found adequate. There are no objections to approval of Davunfite, from a non-clinical and clinical point of view. Bioequivalence between the test and reference product has been adequately demonstrated. The product information is acceptable. The benefit/risk is considered positive, and the application is therefore recommended for approval.

Please refer to section VII.3 for information about conditions regarding educational material.

List of recommendations not falling under Article 21a/22a/22 of Directive 2001/83/EC in case of a positive benefit risk assessment

N/A

List of conditions pursuant to Article 21a/22a or 22 of Directive 2001/83/EC

Additional risk minimisation measures (including educational material)
The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

1. The MAH shall agree the details of a controlled access programme with the National Competent Authorities and must implement such programme nationally to ensure that:

    - Prior to prescribing (where appropriate, and in agreement with the National Competent Authority, dispensing) all healthcare professionals who intend to prescribe (and dispense) <Product name> are provided with an Educational Healthcare Professional's Kit containing the following:
        - o Educational Healthcare Professional brochure
        - o Educational brochures for patients
        - o Patient cards
        - o Risk awareness forms
        - o Information on where to find latest Summary of Product Characteristics (SmPC)

2. The MAH shall implement a pregnancy prevention programme (PPP) in each Member State. Details of the PPP should be agreed with the National Competent Authorities in each Member State and put in place prior to the marketing of the medicinal product.

3. The MAH should agree the final text of the Educational Healthcare Professional's Kit with the National Competent Authority in each Member State prior to launch of the medicinal product and ensure that the materials contain the key elements as described below.

4. The MAH should agree on the implementation of the controlled access programme in each Member State.

Key elements to be included

Educational Healthcare Professional's Kit

The Educational Healthcare Professional's Kit shall contain the following elements:

Educational Healthcare Professional brochure

- Brief background on pomalidomide
- Maximum duration of treatment prescribed
    - 4 weeks for women with childbearing potential
    - 12 weeks for men and women without childbearing potential
- The need to avoid foetal exposuredue to teratogenicity of pomalidomide in animals and the expected teratogenic effect of pomalidomide in humans
- Guidance on handling the blister or capsule of <Product name> for healthcare professionals and caregivers
- Obligations of the healthcare professionals who intend to prescribe or dispense <Product name>
    - Need to provide comprehensive advice and counselling to patients
    - That patients should be capable of complying with the requirements for the safe use of <Product name>
    - Need to provide patients with appropriate patient educational brochure, patient card and/or equivalent tool

Safety advice relevant to all patients

- Description and management of thrombocytopenia including incidence rates from clinical studies
- Description and management of cardiac failure
- Local country specific arrangements for a prescription for pomalidomide to be dispensed
- That any unused capsules should be returned to the pharmacist at the end of the treatment
- That the patient should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of <Product name>

Description of the PPP and categorisation of patients based on sex and childbearing potential

- Algorithm for implementation of PPP
- Definition of women of childbearing potential (WCBP) and actions the prescriber should take if unsure

Safety advice for women of childbearing potential

- The need to avoid foetal exposure
- Description of the PPP
- Need for effective contraception (even if the woman has amenorrhoea) and definition of effective contraception
- That if she needs to change or stop using her method of contraception she should inform:
    - The physician prescribing her contraception that she is on pomalidomide
    - The physician prescribing pomalidomide that she has stopped or changed her method of contraception
- Pregnancy test regime

        - Advice on suitable tests
        - Before commencing treatment
        - During treatment based on method of contraception
        - After finishing treatment
    - Need to stop <Product name> immediately upon suspicion of pregnancy
    - Need to tell treating doctor immediately upon suspicion of pregnancy

Safety advice for men

- The need to avoid foetal exposure
- The need to use condoms if sexual partner is pregnant or a WCBP not using effective contraception (even if the man has had a vasectomy)
    - During <Product name> treatment
    - For one week following final dose
- That he should not donate semen or sperm during treatment (including during dose interruptions) and for 7 days following discontinuation of <Product name> treatment
- That if his partner becomes pregnant whilst he is taking <Product name> or shortly after he has stopped taking <Product name> he should inform his treating doctor immediately

Requirements in the event of pregnancy

- Instructions to stop <Product name> immediately upon suspicion of pregnancy, if female patient
- Need to refer patient to physician specialised or experienced in dealing with teratology and its diagnosis for evaluation and advice
- Local contact details for reporting of any suspected pregnancy immediately
- Pregnancy reporting form

Local contact details for reporting adverse reactions

Educational Brochures for patients

The Educational brochures for patients should be of 3 types:
• Brochure for women patients of childbearing potential and their partner
• Brochure for women patients who are not of childbearing potential
• Brochure for male patients

All educational brochures for patients should contain the following elements:
• That pomalidomide is teratogenic in animals and is expected to be teratogenic in humans
• That pomalidomide may cause thrombocytopenia and the need for regular blood tests
• Description of the patient card and its necessity
• Guidance on handling pomalidomide for patients, caregivers and family members
• National or other applicable specific arrangements for a prescription for pomalidomide to be dispensed
• That the patient must not give <Product name> to any other person
• That the patient should not donate blood during therapy (including during dose interruptions) and for 7 days after discontinuation of pomalidomide treatment
• That the patient should tell their doctor about any adverse events
• That any unused capsules should be returned to the pharmacist at the end of the treatment

The following information should also be provided in the appropriate brochure:

Brochure for women patients with childbearing potential
• The need to avoid foetal exposure
• Description of the PPP
• The need for effective contraception and definition of effective contraception
• That if she needs to change or stop using her method of contraception she should inform:
    - The physician prescribing her contraception that she is on pomalidomide
    - The physician prescribing pomalidomide that she has stopped or changed her method of contraception

• Pregnancy test regime
    o Before commencing treatment
    o During treatment (including dose interruptions), at least every 4 weeks except in case of confirmed tubal sterilisation
    o After finishing treatment
• The need to stop pomalidomide immediately upon suspicion of pregnancy
• The need to contact their doctor immediately upon suspicion of pregnancy

Brochure for male patients
• The need to avoid foetal exposure
• The need to use condoms if sexual partner is pregnant or a WCBP and has no contraception (even if the man has had vasectomy)
    o During pomalidomide treatment (including dose interruptions)
    o For 7 days following final dose
• That if his partner becomes pregnant, he should inform his treating doctor immediately
• That he should not donate semen or sperm during theraoy (including during dose interruptions) and for 7 days after discontinuation of pomalidomide treatment

Patient Card or equivalent tool

The patient card shall contain the following elements:
• Verification that appropriate counselling has taken place
• Documentation of childbearing potential status
• Check box (or similar) which physician ticks to confirm that patient is using effective contraception (if woman of childbearing potential)
• Pregnancy test dates and results

Risk Awareness Forms

There should be 3 types of risk awareness forms:
• Women of childbearing potential
• Women of non-childbearing potential
• Male patient

All risk awareness forms should contain the following elements:
- teratogenicity warning
- patients receive the appropriate counselling prior to treatment initiation
- affirmation of patient understanding regarding the risk of pomalidomide and the PPP measures
- date of counselling
- patient details, signature and date
- prescriber name, signature and date
- aim of this document i.e. as stated in the PPP: “The aim of the risk awareness form is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse reactions associated with the use of pomalidomide. It is not a contract and does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure.”

Risk awareness forms for women of childbearing potential should also include:
- Confirmation that the physician has discussed the following:
    • the need to avoid foetal exposure
    • that if she is pregnant or plans to be, she must not take pomalidomide
    • that she understands the need to avoid pomalidomide during pregnancy and to apply effective contraceptive measures without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment

• that if she needs to change or stop using her method of contraception she should inform:
    ▪ the physician prescribing her contraception that she is taking <Product name>
    ▪ the physician prescribing <Product name> that she has stopped or changed her method of contraception
• of the need for pregnancy tests i.e. before treatment, at least every 4 weeks during treatment and after treatment
• of the need to stop <Product name> immediately upon suspicion of pregnancy
• of the need to contact their doctor immediately upon suspicion of pregnancy
• that she should not share the medicinal product with any other person
• that she should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of <Product name>
• that she should return the unused capsules to the pharmacist at the end of treatment

Risk awareness forms for women with no childbearing potential should also include:
- Confirmation that the physician has discussed the following:
    • that she should not share the medicinal product with any other person
    • that she should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of <Product name>
    • that she should return the unused capsules to the pharmacist at the end of treatment

Risk awareness forms for male patients should also include:
- Confirmation that the physician has discussed the following:
    • the need to avoid foetal exposure
    • that pomalidomide is found in semen and the need to use condoms if sexual partner is pregnant or is a WCBP not on effective contraception (even if the man has had a vasectomy)
    • that if his partner becomes pregnant, he should inform his treating doctor immediately and always use a condom
    • that he should not share the medicinal product with any other person
    • that he should not donate blood or semen during treatment (including during dose interruptions) and for at least 7 days following discontinuation of <Product name>
    • that he should return the unused capsules to the pharmacist at the end of treatment

VII. APPROVAL

The decentralised procedure for Davunfite, 1 mg, 2 mg, 3 mg, 4 mg, Capsule, hard was positively finalised on 2024-11-20.

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report – Update

Procedure number*	Scope	Product Information affected (Yes/No)	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse

*Only procedure qualifier, chronological number and grouping qualifier (when applicable)

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