

## Oral Vinorelbine (Fibromatosis)

### Indication

For use in desmoid fibromatosis when active treatment is indicated

### ICD-10 codes

C49

### Regimen details

Day	Drug	Dose	Route
1, 8 and 15	Vinorelbine	90mg (flat dose)	PO

### Cycle frequency

Every 28 days

### Number of cycles

Usually up to 12 cycles in total

### Administration

Each dose of Vinorelbine is taken as 3 x 30mg capsules swallowed whole with water and with or after food

### Pre-medication

Ondansetron 8mg PO taken 30 minutes before Vinorelbine

### Emetogenicity

This regimen has moderate-high emetic potential

### Additional supportive medication

Metoclopramide (or alternative anti-emetic) if required

H2 antagonist or proton pump inhibitor if required

Mouthwashes as per local policy

Laxatives as required

### Extravasation

N/A

### Investigations – pre first cycle

Investigation	Validity period (or as per local practice)
FBC	14 days
U+Es (including creatinine)	14 days
LFTs	14 days

### Investigations – pre subsequent cycles

Investigation	Validity period
FBC*	96 hours
U+Es (including creatinine)	7 days
LFTs	7 days

\*For cycle 1, an additional FBC and LFT check is required before day 15

### Standard limits for administration to go ahead

If blood results not within range, authorisation to administer **must** be given by prescriber/ consultant

Investigation	Limit
Neutrophils	$\geq 1.0 \times 10^9/L$
Platelets	$\geq 100 \times 10^9/L$
Bilirubin	$< 1.5 \times \text{ULN}$
ALT	$< 3.0 \times \text{ULN}$

### Dose modifications

- Haematological toxicity**

Delay 1 week if neutrophils  $< 1.0 \times 10^9/L$  or platelets  $< 100 \times 10^9/L$  at day 1

Blood tests prior to day 8 and day 15 are not routinely required (except for day 15 of cycle 1). If neutrophils  $< 1.0 \times 10^9/L$  or platelets  $< 100 \times 10^9/L$  omit vinorelbine.

- Renal impairment**

No dose modifications required.

- Hepatic impairment**

If bilirubin  $> 1.5 \times \text{ULN}$  and/or ALT  $> 3 \times \text{ULN}$  delay vinorelbine for 7 days and re-check LFTs.

If toxicity persists beyond 3 weeks or on any single test bilirubin  $> 3 \times \text{ULN}$  or ALT  $> 20 \times \text{ULN}$  discontinue treatment.

- Other toxicities**

Toxicity	Definition	Dose adjustment
Neuropathy	Grade 3 or 4	Discontinue treatment

### Adverse effects - for full details consult product literature/ reference texts

- Serious side effects**

Myelosuppression  
Neurotoxicity  
Infertility  
Hepatic impairment  
Serious birth defects – contraindicated in pregnancy

- Frequently occurring side effects**

Myelosuppression  
Nausea and vomiting  
Mucositis, stomatitis  
Constipation  
Peripheral neuropathy

- Other side effects**

Alopecia  
Fatigue  
Allergic reaction

**Significant drug interactions** – for full details consult product literature/ reference texts

**Warfarin/coumarin anticoagulants:** increased or fluctuating anticoagulant effects. Avoid if possible, consider switching patient to a DOAC or low molecular weight heparin during treatment or if the patient continues taking Warfarin monitor the INR at least once a week and adjust dose accordingly.

**CYP3A4 inducers (rifampicin, barbiturates):** may reduce vinorelbine levels.

**CYP3A4 inhibitors (ketoconazole, erythromycin):** may increase vinorelbine levels.

**Phenytoin:** vinorelbine reduce absorption and efficacy of phenytoin, monitor levels and adjust dose as necessary.

**Itraconazole:** increased risk of neurotoxicity

Ciclosporin, tacrolimus: increased immune suppression and risk of lymphoproliferation

**Additional comments**

Nil

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**References**

- Mir O et al. Long-term Outcomes of Oral Vinorelbine in Advanced, Progressive Desmoid Fibromatosis and Influence of CTNNB1 Mutational Status. Clin Cancer Res. 2020 Dec 1;26(23):6277-6283
- Gennatas S et al. A Timely Oral Option: Single-Agent Vinorelbine in Desmoid Tumors. Oncologist. 2020 Dec;25(12):e2013-e2016
- Vinorelbine for fibromatosis Royal Marsden NHS Trust Protocol
- Summary of Product Characteristics Navelbine (vinorelbine) accessed 16 November 2022 via <https://www.medicines.org.uk/emc>
- Vinorelbine (breast); Somerset, Wiltshire, Avon and Gloucestershire Cancer Alliance (SWAG) chemotherapy protocol, via <https://www.swagcanceralliance.nhs.uk/>

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