Digoxin antibody fragments (Fab) (Digifab) Intravenous for Adults

Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

- **Once Digifab has been administered, there is no clinical benefit in measuring serum digoxin levels** (as the level will represent both free and bound digoxin.)
    - Therefore, it is important to monitor the cardiac status of the patient for at least 24 hours after administration for signs of recurrent toxicity [ref 1]
- **Infusion related reactions or hypersensitivity reactions are possible** - monitor closely for signs of allergic reaction. See Further Information
- Consultation with National Poisons Centre (NPIC) may be advisable in acute overdose situation or if clinical features persist despite treatment [ref 1]
- The onset of response is usually within 30 minutes
- See also **Renal impairment** below
- See **'Monitoring'**overleaf
- Stored in **fridge in ED** with back-up stock in the pharmacy

Available preparations

Digifab 40mg vial

Reconstitution

Water for injection

4ml per 40mg vial

Infusion fluids

Sodium chloride 0.9%

Methods of intravenous administration

Intermittent intravenous infusion (preferred route)

- Dilute required dose with any convenient volume of infusion fluid (suggested volume 100ml [ref

[2)]) and administer over 30 minutes
- If an infusion related reaction occurs, the infusion should be stopped and the patient treated. Consider restarting the infusion at a slower rate [(ref 1,2)]
- The residual volume in the infusion line must be flushed through at the same rate to avoid significant underdosing

Bolus intravenous injection

- If cardiac arrest is imminent Digifab may be given undiluted by rapid injection [(ref 2)]
- An increased incidence of allergic reactions may be expected using a bolus intravenous injection

Dose in adults

A: Cardiac arrest due to digoxin toxicity:

- Urgently administer Digifab as an IV bolus
- Weight greater than 40kg: give 5 vials (200 mg)
- Further doses may be required if an adequate clinical response is not seen after 30 minutes

B: Other indications

- e.g.acute digoxin overdose on top of usual therapy, acute overdose in digoxin-naive patient, digoxin toxicity from chronic therapy - the following calculations can be used to work out the required dose
- Doses below are as per Toxbase, rather than the SPC
- If clinical features persist despite treatment, discuss with Posions centre

The dose depends on the clinical situation and on whether plasma digoxin concentration is available [(ref 1)]

- **B1. When digoxin concentration is available** (measured 6 hours after overdose/last dose, unless urgently indicated in patient with arrhythmia):
    - **Number of vials =**
        - {0.781 x serum digoxin concentration (nanomol/L) x weight (kg)} /200
    - **Round up** to the nearest vial - for convenience, these doses have been worked out in table 1 below

Table 1: Initial dose - when digoxin concentration is available

• As **most assay kits are not designed to measure values above 6.4nmol/L** (5ng/ml),serum digoxin concentration reported may be inaccurate at high levels
• **Important: If clinical features persist despite initial dose, then discuss with NPIC (01) 809 2566 or 01 837 9964**

Example, a patient who weighs 80kg, with a digoxin level of 5.12nanomoL/L- should receive an initial dose of 2 vials

Patient weight (kg)	Serum digoxin concentration (nanomol/L)					
Â	**2.56**	**5.12**	**10.24**	**15.36**	**20.48**	**25.6**
40	1 vial	1 vial	2 vials	3 vials	4 vials	4 vials

60	1 vial	2 vials	3 vials	4 vials	5 vials	6 vials
70	1 vial	2 vials	3 vials	5 vials	6 vials	7 vials
80	1 vial	2 vials	4 vials	5 vials	7 vials	8 vials
100	1 vial	2 vials	4 vials	6 vials	8 vials	10 vials

- **B2. When only ingested dose is available (overdose situation):**
    - **Number of vials = Amount of digoxin ingested (mg) x 0.8**
    - Round up to the nearest vial
    - If clinical features persist despite initial dose, then discuss with NPIC (01) 809 2566 or 01 837 9964
    - Example: if a patient ingested twenty-five tablets of the 0.25mg strength, as an acute single ingestion, (0.25mg x 25 tablets x 0.8) = 5 vials initially

Renal impairment

- It may be expected that excretion of the Fab-digoxin levels complexes from the body is slowed in the presence of renal impairment, and that digoxin may be released after some days from retained Fab-digoxin complexes

General information

- Erroneous dosage calculations may result from inaccurate estimates of the amount of digoxin ingested or absorbed, **or from non steady-state serum digoxin concentrations**
- If after several hours toxicity has not been adequately reversed or appears to recur, re-administration of Digifab at a dose guided by clinical judgement may be required
- If there is no response to an adequate dose of Digifab, the diagnosis of digitalis toxicity should be questioned

Monitoring

- Patients should have **continuous ECG monitoring during and for at least 24 hours after** administration of Digifab
- Monitor temperature, potassium, blood pressure during and after administration

Further information

- **Digoxin serum levels are reported in UHG as nanomol/l.** Toxbase refers to levels in nanogram/ml
- To convert nanomol/L to nanogram/ml multiply nanomol/L by 0.781. For example 2.5 nanomol/L = 1.95nanogram/ml
- The likelihood of hypersensitivity reactions is higher in patients who are allergic to sheep-derived proteins, or to papain, an extract of the papaya fruit, dust mites or latex
- Digoxin antidote has previously been used in two doses: one calculated to neutralise all the digoxin load ('full neutralisation' dose (FND)) and one calculated to neutralise only half of it ('half neutralisation' dose)
    - **Recent evidence indicates that the 'half neutralisation' dose is adequate for most patients.**
    - The dosage information in this monograph is taken from Toxbase. It recommends the use of 'Half-neutralisation doses'.

Storage

- Store at 2 to 8^{0}C
- Do not freeze

References

Package insert and SPC June 2024

1: Toxbase, downloaded 10/04/2025

2:Injectable Medicines Administration Guide Medusa downloaded 10/04/2025

Therapeutic classification

Antidote