Table 137.1. Reported side effects of clofazimine.

System	Frequency	Side effects
Skin	Very common	Discoloration of skin, sweat, hair
		Ichthyosis
	Common	Rash, pruritus
	Uncommon	Photosensitivity reaction, dermatitis acneiform, lymphedema
	Very rare	Exfoliative dermatitis
		Exacerbation of vitiligo
Gastrointestinal	Very common	Nausea vomiting, abdominal pain, diarrhea, discoloured feces
	Uncommon	Gastroenteritis eosinophillc, anorexia
	Very rare	Intestinal obstruction, GIT hemorrhage, abdominal discomfort, constipation
Eye	Very common	Conjunctival disclouration, corneal pigmentation, tear disclouration
	Common	Visual acuity decreased, dry eyes, eye irritation
	Uncommon	Maculopathy, corneal deposits
Blood	Very rare	Lymphadenopathy
		Splenic infarction
		Aplastic anemia
		Methemoglobinemia
Respiratory	Very common	Discoloured sputum
	Very rare	Reversible pulmonary overload
Cardiology	Rare	Cardiotoxicity
		Prolonged QTc interval
Fetal toxicity		Genotoxicity
Renal and urinary	Very common	Discoloured urine
General	Uncommon	Fatigue, increased blood glucose level
	Very rare	Pyrexia
	Common	Weight loss
Neurological	Uncommon	Headache
	Very rare	Dizziness
Psychiatric	Very rare	Depression
Hepatobillary	Very rare	Hepatitis, rise in bilirubin, jaundice, deranged AST

Sources: Data compiled from Barot *et al.*, 2011; Brown-Harrell *et al.*, 1996; Chong and Ti, 1993; Choudari *et al.*, 1995; Dash *et al.*, 1991; Finet *et al.*, 1995; Font *et al.*, 1989; Forster *et al.*, 1992; Goulart *et al.*, 2005; Hameed *et al.*, 1998; Job *et al.*, 1990; Jost *et al.*, 1986; Kaur *et al.*, 1990; Kieu *et al.*, 2012; Lu *et al.*, 2011; Maia *et al.*, 2013; Mathew *et al.*, 2006; Merrett *et al.*, 1990; Mondain-Miton *et al.*, 1994; Moore, 1983; Moreira *et al.*, 1998; Novartis Pharma, 2005; Ohman and Wahlberg, 1975; Oommen, 1990; Patki, 1991; Pavithran, 1985; Philip *et al.*, 2012; Ramachandran and Swaminathan, 2015; Ravi *et al.*, 1993; Salafia and Kharkar, 1987; Singh *et al.*, 2013; Sukpanichnant *et al.*, 2000; Tyagi and Oommen, 1993; Uskudar *et al.*, 2005; Venencie *et al.*, 1986.

1983). Multiple case reports have described a clofazimine enteropathy associated with prolonged high-dose therapy, presenting with severe abdominal pain and gastrointestinal symptoms and may rarely result in gastrointestinal hemorrhage, intestinal obstruction, or malabsorption (Merrett *et al.*, 1990; Uskudar *et al.*, 2005; Chong and Ti, 1993; Jost *et al.*, 1986; Kieu *et al.*, 2012; Mathew *et al.*, 2006; Mondain-Miton *et al.*, 1994; Singh *et al.*, 2013; Sukpanichnant *et al.*, 2000; Venencie *et al.*, 1986; Harvey *et al.*, 1977). In one case death occurred despite cessation of clofazimine (Hameed *et al.*, 1998). These severe presentations may lead to exploratory laparotomy or endoscopic investigation, and hyperpigmented abdominal organs have been described during laparotomy (Hameed *et al.*, 1998), with deposits of red–brown birefringent crystals noted microscopically (Chong and Ti, 1993; Jost *et al.*, 1986; Mathew *et al.*, 2006; Singh *et al.*, 2013; Sukpanichnant *et al.*, 2000). Eosinophilic gastroenteritis associated with clofazimine use has also been reported (Ravi *et al.*, 1993).

6c. Ocular adverse effects

During long-term use, clofazimine crystal deposition may occur in the cornea and conjunctiva causing reddish-brown corneal and conjunctival discoloration (Barot *et al.*, 2011). Kaur *et al.* (1990) performed ocular examination on 76 patients receiving clofazimine for between 6 and 24 months for treatment of leprosy and found conjunctival and corneal pigmentation in 46% and 53% of patients, respectively, although no symptoms resulted. Clofazimine crystals were found in the tears of 32% of these 76 patients. A small number of case reports describe a "bull's-eye" retinopathy associated with long-term clofazimine use (Craythorn *et al.*, 1986; Forster *et al.*, 1992).

7. CLINICAL USES OF THE DRUG

Clofazimine has been primarily used in the treatment of multibacillary leprosy and also in the treatment of multibacillary