- **Uncommon** Asthenia · bladder pain · cough · diarrhoea · dyspnoea · erectile dysfunction · flatulence · hyperhidrosis · hypertension · increased risk of infection · injury · insomnia · oedema · oral ulceration · taste altered · thinking abnormal · urinary tract disorder

- **PREGNANCY** Manufacturer advises avoid—toxicity in *animal* studies.
- **BREAST FEEDING** Present in milk in *animal* studies—manufacturer advises caution.
- **HEPATIC IMPAIRMENT** Manufacturer advises caution in moderate impairment; avoid in severe impairment (risk of increased exposure).
  Dose adjustments Manufacturer advises maximum 7.5 mg daily in moderate impairment.
- **PRESCRIBING AND DISPENSING INFORMATION** The need for continuing therapy for urinary incontinence should be reviewed every 4–6 weeks until symptoms stabilise, and then every 6–12 months.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.
  Modified-release tablet
  CAUTIONARY AND ADVISORY LABELS 3, 25
  - **Emselex** (Merus Labs Luxco II S.a R.L.)
    Darifenacin (as Darifenacin hydrobromide) 7.5 mg Emselex 7.5mg modified-release tablets | 28 tablet PoM £25.48 DT = £25.48
    Darifenacin (as Darifenacin hydrobromide) 15 mg Emselex 15mg modified-release tablets | 28 tablet PoM £25.48 DT = £25.48

F 820

Fesoterodine fumarate

13-May-2020

- **INDICATIONS AND DOSE**

Urinary frequency | Urinary urgency | Urge incontinence

- BY MOUTH
- Adult: 4 mg once daily, increased if necessary up to 8 mg once daily

DOSE ADJUSTMENTS DUE TO INTERACTIONS

- Manufacturer advises max. 4 mg daily with concurrent use of potent inhibitors of CYP3A4; avoid concurrent use in patients who also have hepatic or renal impairment.
- For dose adjustments with concurrent use of moderate inhibitors of CYP3A4 in patients with hepatic or renal impairment, consult product literature.

- **INTERACTIONS** → Appendix 1: fesoterodine
- **SIDE-EFFECTS**
- **Common or very common** Diarrhoea · dry eye · gastrointestinal discomfort · insomnia · throat complaints
- **Uncommon** Cough · fatigue · gastrointestinal disorders · nasal dryness · taste altered · urinary tract infection · vertigo

- **PREGNANCY** Manufacturer advises avoid—toxicity in *animal* studies.
- **BREAST FEEDING** Manufacturer advises avoid—no information available.
- **HEPATIC IMPAIRMENT** Manufacturer advises caution in mild to moderate impairment; avoid in severe impairment (no information available).
  Dose adjustments Manufacturer advises increase dose cautiously in mild impairment; maximum 4 mg daily in moderate impairment.
- **RENAL IMPAIRMENT**
  Dose adjustments Increase dose cautiously if eGFR 30–80 mL/minute/1.73m^2; max. 4 mg daily if eGFR less than 30 mL/minute/1.73m^2.
- **PRESCRIBING AND DISPENSING INFORMATION** The need for continuing therapy for urinary incontinence should be reviewed every 4–6 weeks until symptoms stabilise, and then every 6–12 months.

- **NATIONAL FUNDING/ACCESS DECISIONS**
  Scottish Medicines Consortium (SMC) decisions
  SMC No. 480/08
  The *Scottish Medicines Consortium* has advised (July 2008) that fesoterodine (*Toviaz*®) is accepted for restricted use within NHS Scotland as a second-line treatment for overactive bladder syndrome.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.
  Modified-release tablet
  CAUTIONARY AND ADVISORY LABELS 3, 25
  - **Toviaz** (Pfizer Ltd)
    Fesoterodine fumarate 4 mg Toviaz 4mg modified-release tablets | 28 tablet PoM £25.78 DT = £25.78
    Fesoterodine fumarate 8 mg Toviaz 8mg modified-release tablets | 28 tablet PoM £25.78 DT = £25.78

F 820

Flavoxate hydrochloride

13-May-2020

- **INDICATIONS AND DOSE**

Urinary frequency | Urinary incontinence | Dysuria | Urinary urgency | Bladder spasm due to catheterisation, cystoscopy, or surgery

- BY MOUTH
- Adult: 200 mg 3 times a day

- **CONTRA-INDICATIONS** Gastro-intestinal haemorrhage
- **INTERACTIONS** → Appendix 1: flavoxate
- **SIDE-EFFECTS** Diarrhoea · dysphagia · eosinophilia · fatigue · hyperpyrexia · hypersensitivity · leucopenia · nervousness · vertigo
- **PREGNANCY** Manufacturer advises avoid unless no safer alternative.
- **BREAST FEEDING** Manufacturer advises caution—no information available.
- **PRESCRIBING AND DISPENSING INFORMATION** The need for continuing therapy for urinary incontinence should be reviewed every 4–6 weeks until symptoms stabilise, and then every 6–12 months.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug. Forms available from special-order manufacturers include: oral suspension, oral solution
  Tablet
  CAUTIONARY AND ADVISORY LABELS 3
  - **Urispas** (Recordati Pharmaceuticals Ltd)
    Flavoxate hydrochloride 200 mg Urispas 200 tablets | 90 tablet PoM £11.67 DT = £11.67

F 820

Oxybutynin hydrochloride

24-Jul-2018

- **INDICATIONS AND DOSE**

Urinary frequency | Urinary urgency | Urinary incontinence | Neurogenic bladder instability

- BY MOUTH USING IMMEDIATE-RELEASE MEDICINES
- Child 5-11 years: Initially 2.5–3 mg twice daily, increased to 5 mg 2–3 times a day
- Child 12-17 years: Initially 5 mg 2–3 times a day, increased if necessary up to 5 mg 4 times a day
- Adult: Initially 5 mg 2–3 times a day, increased if necessary up to 5 mg 4 times a day
- Elderly: Initially 2.5–3 mg twice daily, increased if tolerated to 5 mg twice daily, adjusted according to response
- BY MOUTH USING MODIFIED-RELEASE TABLETS
- Child 5-17 years: Initially 5 mg once daily, adjusted in steps of 5 mg every week, adjusted according to response; maximum 15 mg per day

continued →