The Carlat Psychiatry Report

INVEGA (paliperidone ER) Fact Sheet

Manufacturer: Janssen, marketing exclusivity expires 2012.

Indications:
- Schizophrenia.
- Likely to be used off-label for bipolar disorder.

Mechanism: D2 and 5HT 2 receptor antagonist.

Dosing:
- Supplied as extended release tablets in 3 mg white, 6 mg beige, and 9 mg pink (not breakable because of extended release vehicle).
- Manufacturer recommends beginning most patients at 6 mg QAM, which may be the effective dose. However, clinical trials suggest that higher doses are more effective, but also lead to more EPS.
- No dosage adjustment needed for healthy elderly or in moderate hepatic impairment. Dose should be decreased in renal impairment.

Side effects:
- BLACK BOX WARNING: All atypicals may increase mortality in elderly patients by 1.7 times greater than placebo.
- Most common are EPS, akathisia, tachycardia.
- EPS: No more than placebo at 6 mg/day, but increases with higher doses. EPS incidence 26% with 12 mg/day (vs. 11% on placebo).
- Weight gain: Similar to Risperdal. More weight gain liability than Abilify or Geodon, but less than Zyprexa.
- Glucose/Lipids: Not enough data available yet, but will likely be similar to Risperdal (moderate metabolic risk).
- EKG: QT interval widening 12 msec at highest dose tested (8 mg of IR paliperidone, which results in maximum blood levels double that of 12 mg of Invega), similar to Geodon's reported 10 msec QT widening on 160 mg/daily. Also caused tachycardia in 12-14% of patients.
- Prolactin level: Like Risperdal, often causes hyperprolactinemia. Potential symptoms in women are galactorrhea and amenorrhea; in men, gynecomastia and lowered libido.
- Pregnancy Category C

Drug-drug interactions:
- Not metabolized by the liver; excreted unchanged through the kidneys.
- No drug-drug interactions.

Pharmacokinetics:
- Paliperidone is the active metabolite of risperidone.
- Half-life of the ER formulation is 23 hours.