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PRESCRIPTION COMPOUNDING FOR

GENERAL PRACTICE

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AUTISTIC DISORDER

The following review investigates the efficacy and safety of naltrexone in pediatric patients with autistic disorder -"Efficacy and safety of naltrexone use in pediatric patients with autistic disorder" (Ann Pharmacother. 2006 Jun;40(6):1086-95).

OBJECTIVE: To review the efficacy and safety of naltrexone in pediatric patients with autistic disorder (AD).

DATA SOURCES: Using the terms pediatric, child, naltrexone, autism, and autistic disorder, a literature search was performed using MEDLINE (1966-May 18, 2006) and the International Pharmaceutical Abstracts (1971-May 18, 2006) database. The references of these articles were scanned for additional relevant literature.

STUDY SELECTION AND DATA EXTRACTION: All articles describing or evaluating the efficacy and/or safety of naltrexone in pediatric patients with AD were included in this review. Three case reports, 8 case series, and 14 clinical studies were identified as pertinent.

DATA SYNTHESIS: Naltrexone has been used most commonly at doses ranging from 0.5 to 2mg/kg/day and found to be predominantly effective in decreasing self-injurious behavior. Naltrexone may also attenuate hyperactivity, agitation, irritability, temper tantrums, social withdrawal, and stereotyped behaviors. Patients may also exhibit improved attention and eye contact. Transient sedation was the most commonly reported adverse event. Small sample size, short duration, and inconsistent evaluative methods characterize the available research.

CONCLUSIONS: A child affected by AD may benefit from a trial of naltrexone therapy, particularly if the child exhibits self-injurious behavior and other attempted therapies have failed. Serious adverse effects have not been reported in short-term studies. PMID: 16735648

The following case report discusses the successful use of naltrexone for treating a child with severe autistic disorder - "Treatment of a serious autistic disorder in a child with Naltrexone in an oral suspension form" (Encephale. 2009 Apr;35(2):168-72).

ABSTRACT: "...The onset of treatment, at a dose of 1mg/kg/day, led to a transitory increase in negative behavior. However, a dose of 0.75mg/kg per day subsequently led to significant improvements, as shown by outcome measurements. Self-mutilating behavior disappeared completely. Certain side effects were observed, namely transitory sedation at the beginning of treatment and moderate constipation.

CONCLUSION: This clinical case confirms that treatment of a serious autistic disorder in children using Naltrexone in oral suspension form is a potentially interesting therapeutic alternative for treating behavioral symptoms resistant to classical drug therapy. PMID: 19393386

With our state of the art compounding lab and pharmaceutical knowledge and experience, we can compound naltrexone as flavored oral solution that will allow for easy, accurate dosing.

An example of how you might prescribe follows:

COMPOUNDED MEDICATION

Naltrexone 25mg/ml
Flavored Oral Solution
30ml
Give 1ml PO in the evening QD

CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING

This study concluded that topical use of ABH gel appears to be a promising and safe rescue therapy for breakthrough CINV that occurs despite prophylactic antiemetic therapy - "Lorazepam, diphenhydramine, and haloperidol transdermal gel for rescue from chemotherapy-induced nausea/vomiting: results of two pilot trials" (J Support Oncol. 2008 Jan;6(1):27-32).

ABSTRACT: "Despite their use of prophylactic antiemetic therapies, cancer patients continue to consider chemotherapy-induced nausea and vomiting (CINV) to be a significant problem. Patients frequently use various "breakthrough" medications for these symptoms. Unfortunately, there is a paucity of trials regarding treatment of breakthrough CINV.

This study investigated the efficacy of "ABH," a topical gel containing lorazepam (Ativan), diphenhydramine (Benadryl), and haloperidol (Haldol), in reducing breakthrough CINV. Adults receiving standard recommended prophylactic antiemetics as outpatients were instructed to use 0.5 mL of the gel topically when they experienced significant CINV. Patients then were contacted retrospectively to respond to a questionnaire rating their nausea and/or vomiting and their response to ABH-gel treatment.

The results were collected during two trials: Trial I began in April 2003, and Trial II began in March 2006. During Trial I, 23 patients were evaluated; 17 patients (74%) reported that use of the gel decreased their CINV, with 15 (70%) reporting relief within 30 minutes of its application. Three patients believed that the gel caused sedation; no troubles with skin irritation or muscle spasms were reported. In Trial II, all 10 patients believed that the treatment was effective. When the severity of CINV was quantified on a scale of 0-10, the mean CINV score decreased significantly from a 6.1 before gel application to a 1.7 as evaluated 30 minutes following gel application ($P < 0.005$).

Topical use of ABH gel appears to be a promising and safe rescue therapy for breakthrough CINV that occurs despite prophylactic antiemetic therapy. These results warrant further confirmation in a large, randomized, placebo-controlled trial." PMID: 18257398

With our state of the art compounding lab and pharmaceutical knowledge and experience, we can compound lorazepam, diphenhydramine, and haloperidol into one transdermal gel.

An example of how you might prescribe follows:

COMPOUNDED MEDICATION
Lorazepam 1mg/ml + Diphenhydramine 12.5mg/ml + Haloperidol 1mg/ml **Transdermal Gel** 60ml **Apply sparingly to inner wrist TID PRN**

GERD

Omeprazole is an effective treatment for GERD in children, however as the following study notes, dosings on a milligram-per-kilogram basis are recommended -"Pharmacokinetics of omeprazole in healthy adults and in children with gastroesophageal reflux disease" (Ther Drug Monit. 2004 Feb;26(1):3-8).

ABSTRACT: "Studies of the pharmacokinetics of omeprazole in children with gastroesophageal reflux disease (GERD) remain scarce despite the vast number of reports on its efficacy. The objectives of this study were to assess the pharmacokinetics of omeprazole in healthy adults and in children with GERD. Omeprazole (Losec, delayed-release capsules) was administered orally to 18 healthy adults (mean age 36.8 years) and 12 children with GERD (mean age 6.1 years). Blood samples were collected over 5 hours, and plasma concentrations were assessed using liquid chromatography. Population pharmacokinetic parameters were calculated using NONMEM. A 1-compartment model with zero-order absorption and a lag time was used. The population approach was well suited to the limited number of samples available, and residual variability was low. Oral clearance (CL/F) and apparent volume of distribution (V(ss)/F) in healthy adults (Mean +/- SD: 0.62 +/- 0.27 L/h/kg and 0.76 +/- 0.26 L/kg, respectively) were not significantly different than those in children with GERD (0.51 +/- 0.34 L/h/kg and 0.66 +/- 0.25 L/kg, respectively). Healthy adults displayed a statistically significantly longer delay in drug absorption (Lag time: 0.62 +/- 0.15 hours) as compared with that observed in children with GERD (0.12 +/- 0.03 hours, P < 0.05). On the basis of these findings, omeprazole dosings on a milligram-per-kilogram basis are recommended with no further adjustments for the treatment of GERD in children." PMID: 14749542

The following study found that omeprazole 1 mg/kg per day is an effective therapy for the majority of children with severe erosive oesophagitis due to abnormal isolated bile reflux or combined acid and bile reflux -"Treatment of oesophageal bile reflux in children: the results of a prospective study with omeprazole" (J Pediatr Gastroenterol Nutr. 2006 Apr;42(4):376-83).

OBJECTIVES: Reflux of duodenal juice into the oesophagus has a role in the pathogenesis of both oesophageal and laryngopharyngeal inflammatory and neoplastic lesions. As little is known about effective therapy, we studied the effect of proton pump inhibitor therapy on oesophageal bile reflux in children.

METHODS: Twenty-nine children with moderate to severe erosive oesophagitis and abnormal oesophageal bile reflux were studied before and after treatment with omeprazole 1 mg/kg per day. Outcomes included a clinical symptom score, oesophageal acid and bile reflux (simultaneous 24-hour pH and Bilitec 2000 monitoring), and mucosal healing.

RESULTS: After 8 weeks of therapy, 17 (59%) of the patients were symptom-free, and 5 (17%) had minimal symptoms. Mucosal healing or reduction to low-grade oesophagitis was achieved in 25 children (86%; P < 0.0005). Mean percentages of total, upright, and supine time with oesophageal pH less than 4 were reduced from 17.0%, 16.8%, and 19.2% before treatment, to 2.83%, 3.17%, and 2.07%, respectively, after treatment (all P < 0.00001). Similarly, mean percentages of total, upright, and supine time with bile reflux were reduced from 16.96%, 12.67%, and 22.0%, to 2.27%, 1.91%, and 2.23%, respectively (P < 0.000001, P < 0.0001, and P < 0.000001, respectively).

CONCLUSIONS: Omeprazole 1 mg/kg per day is an effective therapy for the majority of children with severe erosive oesophagitis due to abnormal isolated bile reflux or combined acid and bile reflux. It remains unclear how patients with treatment-resistant bile reflux should be managed. PMID: 16641575

An example of how you might prescribe follows:

COMPOUNDED MEDICATION

Omeprazole 2mg/ml
Flavored Oral Liquid
120ml
Give by mouth BID

With our state of the art compounding lab and pharmaceutical knowledge and experience, we can compound omeprazole as an oral liquid that will allow for easy, accurate dosing.

Prescriber Name_____

Prescriber Address_____

City _____ State_____ Zip_____

Phone_____ Fax_____

Date _____ Patient Name_____ DOB_____

Address_____ City/State/Zip_____ Phone_____

☐ Patient will pick up at pharmacy ☐ Please ship to patient

All topical compound %s are per 1 ml or 1 gm unless otherwise noted

Autistic Disorder

[ ] **Naltrexone 25mg/ml** **Flavored Oral Solution**

Quantity 30ml Directions: Give 1ml PO in the evening QD

Chemotherapy-Induced Nausea & Vomiting

[ ] **Lorazepam 1mg/ml + Diphenhydramine 12.5mg/ml + Haloperidol 1mg/ml** **Transdermal Gel**

Quantity 60ml Directions: Apply sparingly to inner wrist TID PRN

GERD

[ ] **Omeprazole 2mg/ml** **Flavored Oral Liquid**

Quantity 120ml Directions: Give by mouth BID

Directions

_____

_____

Prescriber's Signature_____ Refills: 1 2 3 4 5 6 7 8 9 10 11 12 NR

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